

IN THE MATTER OF: "THE MEDICAL ACT, C.C.S.M."  
AND IN THE MATTER OF: DR. SUSAN GRAHAM KRAUSE, A MEMBER OF  
THE COLLEGE OF PHYSICIANS AND SURGEONS  
OF MANITOBA  
AND IN THE MATTER OF: AN AMENDED NOTICE OF INQUIRY DATED  
DECEMBER 13, 2017

## **INTRODUCTION**

On November 2, 2018, a hearing was convened before an Inquiry Panel (the "Panel") of the College of Physicians and Surgeons of Manitoba (the "College") for the purpose of conducting an inquiry pursuant to Part X of *The Medical Act, C.C.S.M.* (the "Act") into charges against Dr. Susan Graham Krause ("Dr. Krause") as set forth in an Amended Notice of Inquiry dated December 13, 2017.

The Amended Notice of Inquiry charged Dr. Krause with professional misconduct, with contravening By-Law 1 of the College, the Code of Conduct of the College, the Code of Ethics of the College, Statements 124 and 108 of the College, and with displaying a lack of knowledge, skill and/or judgment in the practice of medicine, and with demonstrating unfitness to practice medicine.

Among other things, the Amended Notice of Inquiry alleged that:

1. Between in or about February, 2011 and in or about January, 2015, Dr. Krause participated in what was represented to be a clinical research study to investigate an experimental and/or unproven treatment for multiple sclerosis ("MS"), amyotrophic lateral sclerosis ("ALS") and other neurological illnesses in a manner in which Dr. Krause knew or ought to have known was inappropriate and/or unethical. She thereby contravened Statement 124 and Statement 108 of the College and/or one or more of Articles 2, 4, 6, 12, 13, 15, 31 to 31.2.5, 37, 45(a) and (b), 46, 47, 50, 51, 52 and 56 of the College's Code of Conduct and/or demonstrated a lack of knowledge of or a lack of skill or judgment in the practice of medicine and/or committed acts of professional misconduct.

Extensive factual particulars with respect to the above noted allegations were outlined in the Amended Notice of Inquiry.

2. In respect to one or more of 19 patients, all of whom were vulnerable patients, between in or about August, 2012 and in or about January, 2015, Dr. Krause was involved with their participation in a study (the "CTP Study") which was stated to be designed to investigate the safety and efficacy and/or potential benefits of an experimental and/or unproven medical treatment referred to as the Combination Treatment Protocol (the "CTP"). Dr. Krause was also involved in one or more of those 19 patients obtaining the CTP treatment. Dr. Krause provided those patients with medical advice in circumstances in which her personal and/or financial interests conflicted with the patients' interests. Dr. Krause otherwise conducted herself in a manner and in circumstances which Dr. Krause knew was inappropriate and/or unethical. She thereby contravened Statement 124 and/or Statement 108 of the College and/or Articles 1, 2, 4, 6, 12, 13 and 15 of the College's Code of Conduct and/or demonstrated a lack of knowledge of or a lack of skill or judgment in the practice of medicine and/or committed an act or acts of professional misconduct.

Extensive factual particulars with respect to the above noted allegations relating to each of the 19 patients was outlined in the Amended Notice of Inquiry. Those individual patients were referred to in the Amended Notice of Inquiry and throughout these proceedings in a non-identifying way by utilizing the letters A to S inclusive.

3. Between in or about July 30 and September 3, 2013, in response to a complaint then made to the College by Patient B, Dr. Krause failed to cooperate with the College, and/or provide information and/or made statements to the College which she knew or ought to have known, were false and misleading. She thereby contravened Article 41 of the College's Code of Conduct, and/or committed acts of professional misconduct.

Additional factual particulars with respect to the above noted allegations were outlined in the Amended Notice of Inquiry.

4. In circumstances in which Dr. Krause was cooperating with the University of Manitoba in concurrent proceedings and making certain admissions about the nature and extent of her involvement with the operation of the CTP Study and her communications with patients who sought and/or obtained treatment through participation in the CTP Study, between or about February 23, 2015 and on or about April 18, 2017, Dr. Krause impeded and/or failed to cooperate with the College's investigation and/or provided information and/or made statements to the College which Dr. Krause knew or ought to have known were false and misleading. She thereby contravened Article 7 and 50 of the College's Code of Ethics and/or committed acts of professional misconduct.

Extensive factual particulars with respect to the above noted allegations were outlined in the Amended Notice of Inquiry.

5. Commencing in or around February, 2015, Dr. Krause impeded and/or failed to cooperate with the College's investigation by failing to comply with numerous demands to produce relevant records, including demands communicated in letters from the College dated January 2 and 29, 2015 and February 10, 2017. She thereby contravened Articles 7 and 50 of the College's Code of Ethics and/or Section 45(3) of the *Act* and Article 25 of By-Law 1 of the College and/or committed acts of professional misconduct in that she failed to provide complete copies of all records relevant to the investigations in her possession or control as required pursuant to s. 445(3) of the *Act* and Article 25 of By-Law of the College, as was requested in the College's demand letters dated January 20 and 29, 2015 and February 10, 2017.

6. By reason of the foregoing, Dr. Krause demonstrated that she had been either unwilling or unable to fulfill the requirements of and/or be governed by the College.
7. By reason of one or more of the foregoing, Dr. Krause displayed a lack of knowledge of, or a lack of skill and judgment in the practice of medicine.
8. By reason of one or more of the foregoing, Dr. Krause demonstrated an incapacity or unfitness to practice medicine.

The hearing proceeded before the Panel on November 2, 5 and 6, 2018 in the presence of Dr. Krause and her counsel, and in the presence of counsel for the Investigation Committee of the College (the "Investigation Committee"). Dr. Krause, through her counsel:

- (a) admitted her membership in the College, and confirmed that she had no objection to any member of the Panel serving on the Panel;
- (b) acknowledged that all jurisdictional requirements outlined in the *Act* had been met and that the Panel had jurisdiction over the matters at issue;
- (c) acknowledged service upon her of the Notice of Inquiry;
- (d) consented to an order amending the Notice of Inquiry, which order was accordingly granted by the Panel;
- (e) waived the reading of the charges outlined in the Amended Notice of Inquiry.

Counsel for Dr. Krause then asked Dr. Krause a series of questions in the nature of a plea inquiry, whereby Dr. Krause indicated that she had read the Amended Notice of Inquiry and was entering a plea of guilty to charges 1 through 7 inclusive of the Amended Notice of Inquiry. Dr. Krause acknowledged that by doing so she:

- (a) was admitting her guilt with respect to all of the charges;
- (b) had committed acts of professional misconduct;
- (c) the cumulative effect of charges 1 through 5 inclusive of the Amended Notice of Inquiry was that she had been ungovernable, and had displayed a lack of knowledge or a lack of skill and judgement in the practice of medicine;
- (d) she was giving up her right to contest the charges and that she would therefore be the subject of penalties and sanctions to be decided upon and imposed by the Panel.

Dr. Krause entered a plea of not guilty to charge 8, which alleged that she had demonstrated an incapacity or unfitness to practice medicine.

Thereafter, counsel for the Investigation Committee made a motion pursuant to s. 56(3) of the *Act* for an order protecting the identity of all patients and third parties who may be referred to in the proceedings, or who may be referred to in any of the exhibits filed in the proceedings, or in any video, audio or digital recordings to be viewed or referred to as part of the proceedings, except Doug Broeska and Surjo Banerjee. Dr. Krause, through her counsel, consented to such an order.

The Panel, was satisfied that the desirability of avoiding public disclosure of the identities of patients and other third parties referred to in the proceedings and of avoiding public disclosure of the recordings (which in the case of the video and digital recordings featured patients and third parties, and in the case of the audio recordings contained references to patients), outweighed the desirability of the identities of patients and other third parties referred to in the proceedings and in the recordings being made public. The Panel therefore granted an order pursuant to s. 56(3) of the *Act*. The order specified that there shall be no disclosure of the names or identifying information of any patients or other third parties except Doug Broeska and Surjo Banerjee, who may be referred to in the proceedings, or in any of the exhibits in the proceedings and that there

shall be no disclosure, publication or transmission of any video, audio or digital recordings which may be marked as exhibits in or referred to in the proceedings.

During the course of the hearing on November 2, 5 and 6, 2018, several exhibits were filed in the proceedings by consent, including the Notice of Inquiry, the Amended Notice of Inquiry, a detailed Statement of Agreed Facts (consisting of 185 pages and 303 paragraphs) and 3 binders of documents. Binder 1 consisted of general documents relating to the College's pre-2015 investigation, Binder 2 consisted of patient specific documents relating to 21 patients, and Binder 3 consisted of documents relating to the College's investigation from and after January, 2015.

The Panel considered the guilty plea of Dr. Krause to charges 1 through 7 inclusive of the Amended Notice of Inquiry in the context of all of the documentation it received and reviewed and in the context of the submissions received from counsel for the Investigation Committee and counsel for Dr. Krause. The Panel is satisfied that charges 1 through 7 in the Amended Notice of Inquiry have been proven.

The Panel has also determined that charge 8 in the Amended Notice of Inquiry has been proven and that Dr. Krause is therefore also guilty of having demonstrated an unfitness to practice medicine.

The Panel's reasons for its decisions, including its decisions with respect to the penalties and sanctions to be imposed on Dr. Krause pursuant to s.59.6 and 59.7 of the *Act* are outlined below.

## **BACKGROUND**

### **General Background**

1. Dr. Krause was a member of the College at all material times. Her medical training and practice are summarized below:
  - (a) She graduated from the University of Manitoba, Faculty of Medicine (the "University") in 1977 and completed family medicine training in 1990.

- (b) Dr. Krause has been registered in the Manitoba Medical Register since July 1, 1978. She was licensed to practice family medicine in 1990, before which she practiced emergency medicine.
  - (c) Dr. Krause had teaching responsibilities at the Faculty of the Health Sciences of the University, where she held the positions of Undergraduate Director of the Family Medicine Program and Head of the Department of Family Medicine. She was an award winning educator of medical learners.
  - (d) She resigned from the University on August 24, 2015, after having been found by the University's Investigation Committee to have committed breaches of the University's policies with respect to conflict of interest and the University's code of research ethics. The underlying conduct which led to Dr. Krause's resignation relates to many of the same matters which are the subject of these proceedings.
  - (e) She also worked in a full time position at a Winnipeg family practice clinic from 1991 until February, 2015.
  - (f) Dr. Krause has no specialized training in clinical research, neurology, radiology, or stem cell therapies, but cared for patients with MS and ALS in her family practice.
2. Dr. Krause states that she met Doug Broeska in 2006 and shortly thereafter became involved in an intimate, personal and sexual relationship with him, which lasted until October, 2014. Shortly after commencing the romantic relationship with Mr. Broeska, Dr. Krause began advancing money to Mr. Broeska and/or the companies he was operating and in which Dr. Krause had an ownership interest. The first loans were to support the operation of Clinicard Inc. ("Clinicard") a company created by Mr. Broeska to develop a smart card health services product. This product was never

released to the market. In addition to the Clinicard project, Mr. Broeska was also involved in a business venture known as Regenetek Research (“Regenetek”) which promoted and facilitated patients obtaining a form of novel medical therapy, similar to that known as the Liberation Therapy. The therapy promoted through Regenetek was provided to individuals with MS and other diseases through an individual’s participation in what was represented as a clinical research study at a private clinic in Pune, India.

3. The Liberation Therapy is a hypothesized treatment for MS. It was attracting attention in 2009, given a suggested link between narrowed veins in the neck and M.S. Dr. Zamboni, a vascular surgeon and proponent of the Liberation Therapy, hypothesized that “chronic cerebro-spinal venous insufficiency” (‘CCSVI’) could lead to the development of MS and that the Liberation Therapy was a potential treatment for CCSVI and, therefore, MS. The link between CCSVI and MS has been the subject of medical research, but Liberation Therapy has never been sanctioned as a treatment for MS or any other condition in Canada. Many patients with MS have sought and continue to seek treatment with Liberation Therapy outside of Canada. It has never been hypothesized as a treatment for ALS.
4. The specific therapy at the clinic in Pune, India changed over time; but initially involved only the Liberation Therapy and a period of in-patient aftercare. It expanded to include patients receiving injections of stem cells in conjunction with the Liberation Therapy and a course of post-operative physiotherapy. In this latter form, the therapy was referred to as the ‘Combined Treatment Protocol’ (‘CTP’). While initially promoted as an MS treatment, by this particular research group, it was eventually also promoted and offered as a treatment for ALS. In at least two cases, it was provided to patients with neurological symptoms but who were not diagnosed with either of these conditions.

5. As early as 2009, Mr. Broeska asked Dr. Krause to become involved in the study being conducted by Regenetek. This request was made in the context of their then longstanding romantic relationship. Mr. Broeska was married and provided certain information to Dr. Krause about the status of his marriage. Dr. Krause says that she does not know if the information provided by Mr. Broeska regarding the status of his marriage was true or not, but at all times prior to October 2014 she believed that he was interested in having a long term romantic relationship with her.
6. Dr. Krause has always been aware that Mr. Broeska had no formal education or experience in any field of medicine or clinical research and that his education was limited to incomplete undergraduate studies at a university and an online degree in “health administration”, for a part of which she paid.
7. As a result of the investigation conducted by the College, both Dr. Krause and the Investigation Committee have acknowledged that Mr. Broeska can be accurately described as an “effective conman”.
8. Mr. Broeska sought and received Dr. Krause’s financial assistance for both Clinicard and Regenetek. Between 2006 and 2015, Dr. Krause advanced over \$700,000.00 to the operations of Clinicard and Regenetek. Dr. Krause used the equity in her home to borrow money which she then advanced to either Clinicard or Regenetek. She also used her credit cards to obtain cash advances which she then provided to either Clinicard or Regenetek.
9. Commencing in early 2007, Dr. Krause began receiving payments from Clinicard which equaled the monthly payments which she was required to make on her home equity line as a result the money she advanced to Clinicard and Regenetek. She also received lump sum payments as partial repayment of the money she advanced.
10. Dr. Krause has stated that:

- (a) in total, she lost over \$700,000 as a result of her advances to Clinicard and Regenetek; and that
  - (b) she lost her home to foreclosure and was required to make a consumer proposal to her creditors as a consequence of her financial involvement in Clinicard and Regenetek.
- 11. Prior to Dr. Krause meeting Mr. Broeska, she had no disciplinary record with the College.
- 12. The business venture between Dr. Krause and Mr. Broeska included shared involvement in the operation of:
  - (a) Clinicard Inc. (“Clinicard”)
  - (b) Regenetek Research (“Regenetek”), and
  - (c) Regenetek Research Inc.,

all of which were operated out of Winnipeg, Manitoba. The business venture further involved a partnership with an entity called the CCSVI Clinic. It was through this group of entities that the therapy was promoted, facilitated and provided.
- 13. Dr. Krause has stated that initially she was involved as an investor and participated in promoting the therapy being offered, developing methods to screen and qualify individuals seeking the therapy and connecting patients with the clinic in Pune where the therapy was provided. However, from in or about February 2011 through January 2015, Dr. Krause became increasingly involved in active patient engagement, promotion of the therapy and participated in what was represented to be, and what she states she subjectively believed to be, a clinical research study to investigate the therapy as a treatment for MS and over time ALS, that was overseen by Mr. Broeska.

14. The clinical research study will be hereinafter be referred to as “the CTP Study”. The CTP Study:
  - (a) purported to investigate the safety, efficacy and potential benefits of the CTP;
  - (b) registered patients to participate from approximately 2011 to 2014;
  - (c) involved treatment with the CTP at one of two hospitals in Pune, India;
  - (d) purportedly investigated treating patients who had been diagnosed with MS and ALS, with the CTP;
  - (e) was overseen by Mr. Broeska, who was named as the principal investigator; and
  - (f) was operated through Regenetek and Clinicard.
15. Throughout her involvement, Dr. Krause failed to divulge her personal relationship with Mr. Broeska and her financial interest in Regenetek and Clinicard to others, including prospective and enrolled patients, potential and actual investors and the College. This failure allowed her to appear as an independent and unbiased proponent of the therapy, despite her conflicting interests. When engaging patients, she consistently failed to advise them of these conflicts of interests, while providing many with medical advice and promoting the therapy as being an effective treatment for their underlying conditions.
16. Dr. Krause was required to provide details about her involvement with the CCSVI Clinic in 2013 in response to a specific patient complaint to the College. The complaint was from Patient B. The complaint stated that Dr. Hauch (now know as Dr. Krause) wrote a letter for Patient B, who was not a patient of Dr. Krause and was a person that she had never met, so

that Patient B could obtain a visa to go to India to undergo treatment with the therapy offered through the CCSVI Clinic for his MS.

17. In a written response to that complaint, she denied any active involvement with the CCSVI Clinic and deliberately made significant false and misleading statements to the College. By doing so, she successfully misled the College and diverted its attention away from serious concerns about her conduct as a physician, including the nature and extent of her inappropriate involvement in the controversial therapy and the CCSVI Clinic.
18. Significant concerns about Dr. Krause's conduct and involvement with the CCSVI Clinic, Regenetek and Clinicard resurfaced in a series of investigations following a referral from the Registrar in January 28, 2015. The Registrar's referral was based in part on various media reports and information provided from a former employee of Regenetek. An excerpt from one of the numerous news articles that quoted Dr. Krause, published January 18, 2015, states as follows:

The Winnipeg physician who worked closely with a now discredited medical researcher says she was "duped" by [Mr. Broeska] and is shocked by recent revelations.

"Scammed, yes. Duped, yes," said [Dr. Krause], a physician and associate professor at the University of Manitoba medical school. "We've all been duped."

She said she's shocked by news [Mr. Broeska] inflated his credentials, overstated the effects of the stem cell treatment and was asked recently by an Indian ethics committee to resign as the study's principal investigator because he put patient safety at risk. "It's very unfortunate things had to come out this way because it's shattered a lot of lives," [Dr. Krause] said by phone Sunday. "This has been a very shocking situation."

[Emphasis added]

19. Following the Registrar's referral, 5 complaints were received from patients, between January 28, 2015 and June 3, 2015. Each similarly alleged that Dr. Krause and Mr. Broeska jointly marketed the CTP procedure to them.

All patients advised that Dr. Krause provided medical advice in this context. The complainants felt that the CTP procedure and CTP Study constituted a fraudulent scheme and that Dr. Krause's professional judgment had been jeopardized by her business interests.

20. Dr. Krause initially was unable to participate in the College investigations in January 2015 due to health concerns related to her reaction to the investigation and the publicity of her involvement with Mr. Broeska and Regenetek. When she first responded to the allegations, she vehemently denied many of the allegations which she ultimately admitted. In her first interview with the College in June 2015, she described being scammed by Mr. Broeska and described the business venture as medical tourism.
21. It took over two years of intensive investigation, during which Dr. Krause changed her stance several times and failed to divulge or admit the full nature and extent of her involvement, before the College finally terminated its investigation and brought charges based on the facts outlined herein. It is significant that it was not until the Fall of 2016, after Dr. Krause was confronted about positions that she took in an investigation that had been concurrently undertaken by the University in 2015 and after she changed legal counsel that she began to take significant steps towards acknowledging the full nature and extent of her misconduct over the preceding years, including during the investigation.
22. During the course of the College's investigation, Dr. Krause was compelled to produce records relevant to her involvement in these matters. The records which she produced included e-mail correspondence in which she either actively participated or was copied by the sender. Concerns about her failure to cooperate with the College and to make timely production at various stages in the investigation include:
  - (a) Production of much of the e-mail communication which was ultimately provided by Dr. Krause was inexplicably delayed, and, in

some cases, certain e-mails were inexplicably redacted or otherwise altered.

- (b) Several e-mails provided by other witnesses during the College's investigation, which should have been in Dr. Krause's possession, and therefore should have been produced by Dr. Krause, were not produced by her.
23. Dr. Krause has stated that, at all material times, she subjectively believed that she was attempting to help those patients who participated in the CTP Study and/or who received the CTP. Dr. Krause now admits that she failed to assess with the appropriate degree of rigour expected of a physician with her education, training and experience, whether The CTP Study could scientifically determine the efficacy of the therapy given the way it was designed and conducted. She also admits that her involvement with the promotion of the CTP Study, therapy and provision of medical advice to patients as a physician was inappropriate and unethical. Dr. Krause has stated that her misconduct is the result of an overriding emotional and financial conflict of interest.

Personal Financial and Business Relationships, the CTP and the Operation of the CTP Study

24. Dr. Krause has stated that she and Mr. Broeska were involved in an intimate personal and sexual relationship between 2006 and 2014. Dr. Krause has also stated that she has had no contact with Mr. Broeska since mid-January 2015.
25. On June 18, 2015, during an interview with the College's investigator, Dr. Krause described Mr. Broeska as someone who had been "controlling", "dishonest" and "manipulative" and from time to time, both verbally and physically abusive. She stated that her professional judgment was profoundly impaired by her relationship with Mr. Broeska during her involvement with him.

26. Clinicard was a company created by Mr. Broeska in which Dr. Krause:
- (a) became involved in approximately 2008, when she was invited by Mr. Broeska to become an investor;
  - (b) was an officer and shareholder;
  - (c) was a creditor of and from which she directly received regular monthly payments and periodic lump sum payments;
  - (d) by approximately 2010, had become a guarantor for a significant portion of its debt; and
  - (e) advanced more than \$700,000.00.
27. Regenetek was a business venture overseen by Mr. Broeska and in which Dr. Krause was extensively involved and which:
- (a) was developed in late 2010 or early 2011 by Mr. Broeska and Dr. Krause to carry on the business of vetting of patients with ALS and MS for participation in what was represented to be a clinical research study called the CTP Study (“CTP Study”); and
  - (b) operated a website, primarily at the direction of Mr. Broeska, with respect to which Dr. Krause was regularly consulted regarding content, which described and promoted the CTP Study and/or the CTP procedure.
28. The articles of incorporation for Regenetek Research Inc. describe it as a not-for-profit. Dr. Krause had a shared interest in Regenetek Research Inc. with Mr. Broeska as a director and creditor. It was created in 2014 to conduct an adjunct clinical research study (“The Physiotherapy Study”) with one of its stated goals being to investigate the safety and efficacy of a course of physiotherapy in patients after they had undergone the CTP

procedure that was to be carried out in affiliation with the University of Winnipeg.

29. Dr. Krause provided direction and financial support to Regenetek, Clinicard and Regenetek Research Inc., with the goal of benefiting financially from her involvement with Mr. Broeska and those three entities. By way of example:

- (a) In an e-mail dated June 3, 2012 to Mr. Broeska, Dr. Krause wrote

“Also thank you for your diligence in regards to the financial side of the business. I apologize if I got a bit “edgy” yesterday. The tax bill is a bit daunting and I was feeling a bit vulnerable. However your financial projections are reassuring and the offer of \$25,000 from the August bookings would be most helpful and truly appreciated. After that, we can review the situation and revise the amounts.”

Dr. Krause has stated that while Mr. Broeska advised she would be provided with \$25,000, she was only paid \$6,400 in accordance with his plan.

- (b) In an e-mail dated January 29, 2013, Dr. Krause asks for \$8,000 from Clinicard.

#### Provision of the CTP and the Operation of the CTP Study

30. CTP was an acronym which became the term used for the “treatment”/therapy being offered to patients. It involved surgical intervention with a specific venoplasty procedure, a form of which is known as the Liberation Therapy. It also involved injections of stem cells, which had previously been harvested from the patient.
31. The CCSVI Clinic:
- (a) was primarily involved with organizing patient access to the CTP in Pune, India;

- (b) maintained a website which described and promoted the CTP Study, [www.ccsviclinic.ca](http://www.ccsviclinic.ca);
  - (c) was primarily controlled, operated and managed by Mr. Surjo Banerjee (“Mr. Banerjee”), an Indian national, and Mr. Broeska;
  - (d) oversaw the CTP procedure being carried out at one of two hospitals in Pune India; and
  - (e) was involved in a partnership with Clinicard and Regenetek through which Mr. Broeska and Dr. Krause were able to influence the operations of the CCSVI Clinic.
32. The CTP and the CTP Study were described in a document that was represented by Regenetek, Mr. Broeska and Dr. Krause as a scientific research protocol (“CTP Study Protocol”). There are several versions of this document, but all are titled ‘*The Autologous Stem Cell Therapy in the Treatment of Patients with Neurodegenerative Disorders*’.
33. In the ordinary course, patients were required to pay a fee, sometimes as high as \$45,000.00 USD, to Clinicard to be included in the CTP Study and/or to be treated with the CTP in Pune as part of the CTP Study. In the case of at least Patient L, the fee also included participation the Physiotherapy Study after it was developed by Mr. Broeska and Dr. Krause to be operated through Regenetek Inc. in or about 2013. Dr. Krause was aware that fees in varying amounts were being charged, though she maintains that she did not know the precise amount that some patients paid.
34. Between May, 2010 and December, 2014, Dr. Krause participated in extensive e-mail communications with others, including Mr. Broeska and Mr. Banerjee, which demonstrate her participation in the activities of the CCSVI Clinic and the CTP procedure being carried out in Pune, India and in the CTP Study. By way of example:

- (a) On December 14, 2010, Mr. Broeska sent an e-mail to Dr. Krause with draft language for her to review, to describe the services offered through the CCSVI Clinic and how they compared with other sites performing the standard "Liberation procedure". Dr. Krause replied: "Thanks, this is most helpful";
  - (b) An e-mail dated April 8, 2014 from Patient L's husband, conveying his impression that Dr. Krause was a medical consultant for the CCSVI Clinic;
  - (c) An August 20, 2014 e-mail thread in which Dr. Krause participated concerning patient fees and related dealings with the CCSVI Clinic;
  - (d) A December 14, 2014 e-mail thread, on which Dr. Krause was copied, in which Mr. Broeska and Mr. Banerjee discussed Mr. Broeska's removal as principal investigator from the CTP Study.
35. From the Fall of 2012 through January 2015, Mr. Broeska and Dr. Krause unsuccessfully undertook efforts to expand their business operations through the development of new clinics where the CTP procedure could be performed in the Cayman Islands (fall 2012 - summer 2013), the Bahamas (summer 2013-fall 2014), and Trinidad and Tobago (summer 2014 - January 2015). Dr. Krause was extensively involved in these plans and the many discussions about CCSVI Clinic/Regenetek's Trinidad and Tobago expansion, patient recruitment and cost to patients undergoing the CTP procedure that took place both in person and via e-mail. Regenetek and the CCSVI Clinic were ultimately unsuccessful in their efforts to expand out of Pune, India.

#### Concerns About the CTP Study and Dr. Krause's Role

36. Through her involvement with Mr. Broeska and the above named entities, from 2006 through January, 2015, Dr. Krause participated in the creation,

promotion, written content and operation of the CTP Study and the CTP Study Protocol.

37. Dr. Krause assisted Mr. Broeska in the drafting of the CTP Study Protocol in the spring of 2011. In an e-mail exchange dated February 14, 2011, Mr. Broeska and Dr. Krause discussed the methods section of the draft study protocol. The CTP Study Protocol changed several times from its original iteration in 2011 through to the termination of Dr. Krause's involvement in the CTP Study in early 2015. In at least one version of the CTP Study Protocol, Dr. Krause was referenced as a founding researcher and her name appeared on the cover, although Dr. Krause maintains that she was unaware of this version of the CTP Study Protocol.
38. Examples of the nature and extent of Dr. Krause's involvement in the content of the CTP Study Protocol and her involvement in attempting to conceal or minimize her involvement are outlined below:
  - (a) Dr. Krause maintains that she at no time viewed the original iteration of the CTP Study Protocol that would have been reviewed in the spring/summer of 2011 by the Independent Ethics Committee, Pune.
  - (b) Dr. Krause was provided with a new version of the CTP Study Protocol by Mr. Broeska for review in July of 2013, shortly after she was made aware of Patient B's complaint to the College. This version added the stem cell injections/infusions that were part of the CTP procedure. Dr. Krause provided a copy of this version of the CTP Study Protocol to the College in February 2015.
  - (c) Dr. Krause noted in her July 30, 2013 letter to the College that she had read a version of the CTP Study Protocol. She further acknowledged reading a version of the CTP Study Protocol in her interview at the College on June 18, 2015 though stated she had

never seen a version of the protocol with her name on it and only saw the version that included stem cell infusion.

- (d) In a letter dated June 26, 2013, Mr. Broeska sent a version of the CTP Study Protocol to the College of Licensed Practical Nurses of Manitoba (“CLPNM”) in relation to an investigation of one of its members, concerning that member’s involvement with Mr. Broeska and the CCSVI Clinic. It was like the version of the CTP Study Protocol that Dr. Krause produced to this College in February of 2015, though in the copy Mr. Broeska provided to the CLPNM, Dr. Krause’s name is listed on the cover. Dr. Krause maintains she was unaware of this version of the document.

39. The CTP Study was represented to have been approved by a body called the “Independent Ethics Committee” (“IECP”) on August 15, 2011. Dr. Krause has stated that she became aware that the individual represented to be the chair of the IECP that approved the CTP Study Protocol later became the principal investigator of the CTP Study, after Mr. Broeska was removed by the IECP and was involved in the possible expansion of the CCSVI Clinic to Trinidad and Tobago in later 2014. Both of those developments represent a clear conflict of interest that would not have been acceptable by Canadian Research Ethics Boards’ standards [such as the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, TCPS2, 2014].
40. The Investigation Committee obtained an opinion from an expert consultant neurologist who specializes in MS and related neuro-immunological conditions and has significant experience participating in clinical trials as a researcher. He has opined that the design and implementation of the CTP Study, as described in the CTP Study Protocol, rendered it incapable of producing meaningful results given the following, cumulatively and individually:

- (a) No control group was established without any apparent rationale.
- (b) No data collection occurred prior to patients receiving the CTP.
- (c) No reasonable or appropriate inclusion and exclusion criteria for patients was established.
- (d) The disease under study was not adequately defined in the CTP Study Protocol or anywhere else.
- (e) The CTP Study Protocol contained inappropriate content - for example providing details as to the transport of sperm, which is completely unrelated to any aspect of the study.
- (f) The CTP Study Protocol described inappropriate means for collecting data and interpreting results in the circumstances.
- (g) Standardized procedures for carrying out the CTP were not established.
- (h) The nature of the treatment under study was not adequately identified or described.
- (i) Patients were charged a fee to participate in the CTP Study.
- (j) The informed consent documentation used in conjunction with the CTP Study Protocol did not meet the standard of the profession.
- (k) The CTP Study Protocol changed one or more times during the CTP Study.
- (l) Several participants were removed from the study without regard to the impact that these changes would have on the validity of the results of the CTP Study.

41. The expert consultant neurologist engaged by the Investigation Committee concluded that:

As the trial, as (inconsistently) described in the protocol, would not allow the collection of any meaningful data to advance care of MS and/or other neurological conditions it would be fundamentally unethical to proceed with such research.

[...]

I have described my general and specific concerns with the clinical trial above. Recognizing that these interventions are a highly specialized area of clinical research, I would personally not expect physicians in general, including family physicians, to have an appreciation of the biology of MeSCs or standard clinical trial procedures for neurological conditions including multiple sclerosis. Nevertheless, as the multiple points I have made indicate, there are significant problems throughout the protocol that could have been identified without any expertise in neurological clinical trials.

#### The CTP Study as a Means of Promoting the CTP Procedure

42. Dr. Krause knew the CTP procedure was an experimental, non-traditional therapy, which was not a proven treatment for any disease. Nonetheless she provided input as to the wording of the Mission Statement for the proposed expansion of Regenetek/CCSVI Clinic operations in the Cayman Islands.
43. Regenetek and the CCSVI Clinic relied on referrals and recommendations as a means of promoting patient access to the CTP and encouraging patients to participate in the CTP Study in exchange for payment of a fee. To that end, it maintained an online presence that included social media through a Facebook group and websites operated by Regenetek and the CCSVI Clinic.
44. Patient postings on the websites and in the Facebook group were closely monitored by Mr. Broeska. Medical advice was commonly offered to people who posted on Regenetek's website, the CCSVI Clinic website or the

affiliated Facebook group and Dr. Krause was involved in the content for the websites and the Facebook page, including contributing to articles, drafting, reviewing and editing text and providing medical advice and other information for publication on the website(s).

45. Dr. Krause was involved in the production of promotional videos featuring Patients F, T, A and U in 2012 and 2013. Those videos were accessible on the website and to members of the Facebook group and shared with potential investors and prospective patients. Her activities included participating in the editing and drafting the commentary. Dr. Krause is seen in the video and endorsed the content of an e-mail that Mr. Broeska intended to send to a physician extolling the benefits of treatment at the CCSVI Clinic.
46. On November 3, 2013, Mr. Broeska e-mailed X, a person who Dr. Krause states that Mr. Broeska believed “would be a good contact in Saskatchewan”. The e-mail was copied to Dr. Krause, and falsely stated that Patient A was a quadriplegic patient who had “end-stage MS”, that Patient T, another CTP Study participant, “lost most if not all of her neurological deficits”, and that the organization had “treated about 60 MS, ALS and Parkinson’s patients, all with similar outcomes.”
47. Dr. Krause responded to Mr. Broeska’s November 3, 2013 e-mail to X stating, “The letter to [X] is very well done. Excellent documentation of information and the important timelines that are relevant to our protocol and study to date.” [emphasis added]. In this context, it is important to note that Dr. Krause was aware that:
  - (a) Patient A had not been diagnosed with end-stage MS and was not quadriplegic.
  - (b) The statement that, “In the past 2 years we have treated about 60 MS, ALS and Parkinson’s patients, all with similar outcomes”, which

Mr. Broeska also made on many other occasions to others, was blatantly false.

48. In response to a request from Dr. Krause for money from Clinicard, an e-mail exchange occurred on October 9, 2012 between Mr. Broeska and Dr. Krause demonstrating the link between the purpose of the videos and her financial interest and is evidence of a clear conflict of interest. Mr. Broeska wrote, among other things:

“I’ll be able to write that cheque as soon as the next patient money comes in, ok? ...it’s starting to get better now and we are starting to book patients regularly with the help of the videos and the good uptake by the MS community.”

Dr. Krause responded:

“Ok...thanks for the \$\$\$ update when you’re able to do so, that would be much appreciated yes...the patient videos have been most productive and positive.

It should allow for the recruitment of the patient numbers that we need to sustain a revenue flow and profit.”

49. Dr. Krause assisted with writing the following articles which were published on the Regenetek website on or about the following dates:
- (a) July 14, 2014 titled, ‘Noted Skeletal Muscle Transformation in Patients with Multiple Sclerosis Having Undergone Regenetek’s Stem Cell CTP’.
  - (b) August 4, 2014, comparing the CTP with “HSCT” and highlighting concerns with “HSCT” as a treatment for MS in comparison to the CTP.
  - (c) September 30-October 1, 2014 titled ‘Combination Therapy for MS Explained’, which detailed the CTP procedure.

- (d) October 4, 2014 which described the rationale for using stem cells in conjunction with venoplasty in treating patients with MS.

Concerns About the Conduct of CTP Study and the Physiotherapy Study

50. Some of the patients who were experiencing symptoms consistent with their neurological illness post-CTP, were advised by Dr. Krause, directly or through Mr. Broeska, that their symptoms were likely attributable to an unrelated factor. Dr. Krause, personally or in complicity with Mr. Broeska, looked for explanations as to why these individuals were not responding which explanations generally downplayed or failed to concede that it was possible that the symptoms were related to the underlying neurological illness which the CTP was intended to treat.
51. Diet and medications were frequently identified by Dr. Krause and Mr. Broeska as factors possibly undermining the efficacy of the stem cells which were purportedly injected as part of the CTP procedure. As part of this effort, Dr. Krause developed, maintained and updated a list of foods, supplements and medications she advised patients to avoid while participating in the CTP Study.
52. The consultant retained by the College has stated that there is no evidence that supports the conclusion that particular foods or medications would impact stem cells. The consultant has written:
- In research work to date, I have not encountered any research to suggest that the multi-faceted effects of mesenchymal stem [MeSC] cell administration are altered by any other specific medications, supplements or foods....
53. Another comorbidity suggested by Dr. Krause and Mr. Broeska as a confounding variable was spinal stenosis. As an example, in an e-mail dated September 28, 2014, regarding one CTP Study participant, PT A, Dr. Krause suggested medications, supplements and spinal stenosis could account for PT A's lack of recovery post-CTP procedure with little regard for

the fact that her symptoms were also consistent with her underlying neurological disease which the CTP was intended to treat. As noted elsewhere, Dr. Krause had no expertise in the areas of neurology and radiology.

54. Dr. Krause acknowledged at her interview with the College on June 18, 2015 that she was aware of at least two CTP Study participants who were excluded from the CTP Study for “bad behaviour”.
55. After one of these patients was “dismissed from the study”, Dr. Krause assisted in providing a “Disruptive Behaviour Document” for the CTP Study.
56. Dr. Krause was extensively involved in the development of the Physiotherapy Study from its inception in 2013 through January of 2015. The Physiotherapy Study was intended to be carried out by Regenetek Research Inc. in collaboration with Y, who was a physiotherapy professor with the University of Winnipeg. Dr. Krause’s involvement in the development and promotion of the Physiotherapy Study was, at least in part for the purpose of lending credibility to the CTP and CTP Study and to improve the business prospects of Regenetek, Clinicard and the CCSVI Clinic.
57. Conflict of interest concerns in relation to the CTP procedure and the Physiotherapy Study were always significant in communications between Dr. Krause, Mr. Broeska, Y and the University of Winnipeg administration. Y stated throughout the relationship with Dr. Krause, Mr. Broeska and Regenetek, that the Physiotherapy Study could not be connected to Regenetek’s business affairs or patient recruiting and that the University of Winnipeg was not to be seen to be promoting CTP procedure. The University of Winnipeg was to be in no way involved in recruitment for the CTP procedure. He also made clear that participation in the Physiotherapy Study was to be provided at no cost to patient participants and that patients were not to be involved in the funding of the Physiotherapy Study.

Mr. Broeska and Dr. Krause represented to the University of Winnipeg that this was acceptable and stated that patients were not funding the research.

58. Dr. Krause wrote to Y on August 1, 2013, confirming her representation to him that the Physiotherapy Study had nothing to do with recruitment of patients for the CTP Study.
59. On May 26, 2014, Mr. Broeska sent an e-mail to various University of Winnipeg administrators, potential Regenetek investors, and Y describing the ethical integrity of the CTP Study being carried out by himself, Dr. Krause and others. Mr. Broeska falsely asserted again that the Physiotherapy Study would not be used to promote the CTP procedure and made numerous other significant misrepresentations throughout the e-mail. Dr. Krause approved the content of the e-mail before it was sent.
60. Y had the impression that Dr. Krause had no financial interest in the provision of the CTP procedure, or in Regenetek. Dr. Krause represented to Y that she wanted to be seen to be an investigator with the Physiotherapy Study and not be seen as involved in the CTP procedure.
61. Regarding funding, Mr. Broeska initially proposed to the University of Winnipeg that Regenetek would provide funding for the Physiotherapy Study, however this was not acceptable to the University of Winnipeg. The University of Winnipeg wanted to ensure the study was unbiased, thus funding was not to be connected to Regenetek and the CTP procedure. Mr. Broeska advised he would find an independent entity to provide full funding to start the Physiotherapy Study. It was at that time that Z and Mr. Broeska, on behalf of Regenetek, developed a relationship with TGCF, an organization that was meant to act as a trustee for funds raised for the Physiotherapy Study. Y was not advised whether patients were providing funding to TGCF for their own research, but did advise that if that did happen, it would present a bias. Dr. Krause was aware of Y's concern in this regard.

62. Dr. Krause and Mr. Broeska attempted to use TGCF as an intermediary trustee for funds paid by CTP Study participants, which could then be funneled for use in the Physiotherapy Study. It was their intent to conceal from Y and the University of Winnipeg that the funds were solicited by Regenetek from patients to pay for the Physiotherapy Study. This allowed Dr. Krause and Mr. Broeska to circumvent the University of Winnipeg's ethics concerns about conflicts of interest.
63. The University of Winnipeg terminated their involvement in the Physiotherapy Study after determining it would not grant ethics approval for the study in January of 2015.
64. AA was hired by Regenetek to assist with the Physiotherapy Study and the CTP Study as she possessed a specialty in research related to neuro-imaging analysis. Consideration was being given at that time to add an imaging component to the CTP Study. AA advised that she first encountered Dr. Krause and Mr. Broeska in May of 2014. AA officially commenced work with Regenetek in September of 2014.
65. AA, Dr. Krause and Mr. Broeska frequently discussed the CTP Study and the Physiotherapy Study in the summer of 2014. No formal divide between the two studies was established by the group at any time. At that time, the design and conduct of the CTP Study and the Physiotherapy Study remained in their preliminary stages of development. In subsequent months, AA would identify significant issues with:
  - (a) the data, or lack thereof, collected during the CTP Study;
  - (b) the data collection methods employed by Mr. Broeska;
  - (c) the inclusion and exclusion criteria;

- (d) unfounded claims and publication of promotional materials;
- (e) charging patients significant fees;
- (f) encouraging patients to discuss their recovery amongst one another;  
and
- (g) the drafting of the CTP Study Protocol.

66. Dr. Krause put her mind to exclusion criteria regarding co-morbidities in the summer of 2014, approximately three years after the CTP Study purportedly commenced, to address increasing numbers of patients that were asserting they did not respond to the CTP procedure.

From: SUSAN HAUCH

Sent: August-13-14 10:21 AM

To: [Mr. Broeska]

Subject: Re: medical term needed

Not sure. There is a condition known as Multi-system atrophy, (MSA) that is a neurologic condition, only. I don't believe that it is of a known autoimmune origin.

As for, chronic fatigue, fibromyalgia, bursitis, endometriosis. They are NOT of autoimmune origin and have other etiologies. To put them into the same class of disease as MS is not appropriate. Therefore, the term would most definitely not be correctly defining the issues at hand.

The diagnoses listed are a huge disease burden for one patient and personally I don't think it's appropriate to treat someone with these many issues. The number and types of medication that they will likely be on would exclude them from the treatment, from the get go, regardless of anything else.

I would not treat a patient with MS and fibromyalgia for 2 reasons. The fibromyalgia will likely not be improved and those with fibromyalgia have many psychological issues as well.

You and I most definitely need to outline a more exhaustive exclusionary criteria list.

---

From: [Mr. Broeska]

To: "SUSAN HAUCH"

Sent: Wednesday, August 13, 2014 10:32:17 AM

Subject: RE: medical term needed

Brilliant! Thank you for that great explanation.

As I encounter more and more of these patients with multiple diseases, I am sympathetic to their stories and want to help, but ultimately we cannot. So developing clear guidelines and policies here is important. You raised a very important point about psychological issues as well. We need better criteria to assess this to exclude them, as in [Patient J]'s case, because ultimately these patients will not be compliant, MAY be disruptive and WILL bias the study, no matter how many papers they sign.

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From: SUSAN HAUCH

Wed, Aug 13, 2014 09:41 AM

Subject: Re: medical term needed

To: Doug Broeska

Thank you!!

yes .... I totally agree with you on all comments. Will put my "thinking" cap back on lol!

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From: SUSAN HAUCH

Wed, Aug 13, 2014 02:47 PM

Subject: Exclusionary criteria.

To: [Mr. Broeska]

1 attachment: Exclusionary criteria CTP treatment.doc - 23 KB

Here's a few thoughts on some exclusionary criteria to add to the existing list.

The wording may need to be changed a bit and you may wish to remove some.

67. AA reviewed the information and data collected under the CTP Study that she was provided by Mr. Broeska at the time of her arrival. She felt that the group would not be able to publish any kind of pilot study based on that data. AA was never able to put together adequate data for publication, partly because data was not always complete. AA also expressed this concern to both Dr. Krause and Mr. Broeska.
68. Data was only ever provided to AA in relation to twelve (12) patients. AA recounts that Mr. Broeska frequently advised her not to worry about obtaining the research data. The data received from the twelve (12) patients that she was provided was from various points in time. It appeared to be from patients that had received the treatment and were followed for about a year. AA reviewed this data and found it to be promising. However, she later observed Mr. Broeska collecting the kind of data she was looking at from a Regenetek client and became skeptical concerning his methods. Mr. Broeska had called the patient and requested the patient to retrospectively advise how they felt at very points in the past. He would record their response. The collection of data was not contemporaneous.
69. Dr. Krause was aware that patients generally paid a fee to be included in the CTP Study and/or be treated with the CTP and/or undergo a post-CTP course of physiotherapy, which generally ranged from \$15,000-45,000 USD.

70. AA and Dr. Krause discussed the cost of the CTP procedure as a potential confounding variable that could enhance the placebo effect and otherwise affect the reliability of the results. No resolution of this issue was ever reached.
71. Patient A was often used by Mr. Broeska and Dr. Krause as an example of the success of the CTP procedure and a video of Patient A that Dr. Krause appears in was used as a promotional tool. Mr. Broeska advised AA that Patient A had MS. Dr. Krause implied that Patient A had MS and never corrected Mr. Broeska when he indicated that Patient A had MS.
72. In the fall of 2014, AA advised the group to do a case study on Patient A and publish same. She requested Patient A's chart, which she eventually received in part. Dr. Krause participated in planning the design and encouraging the publication of a case study of Patient A. Patient A did not have a definitive diagnosis for her neurological condition and it was always unclear whether the placebo effect and her post-CTP procedure physiotherapy regime could have accounted for any benefit demonstrated after she received the CTP. AA concluded upon reviewing materials made available to her that it did not appear as though Patient A had MS. She suggested to Dr. Krause that the diagnosis be reviewed.

#### The End of the Regenetek/CCSVI Clinic/Mr. Broeska/Dr. Krause Relationships

73. Dr. Krause's and Mr. Broeska's relationship with the CCSVI Clinic began to unravel in the fall of 2014.
74. In a letter dated December 10, 2014, a copy of which Dr. Krause provided to the College in February of 2015, Mr. Broeska was notified by the Independent Ethics Committee in Pune that it determined conduct of the CTP Study "considerably deviated from the International Good Clinical Practice Guidelines and Declaration of Helsinki, and have violated international ethical standards." On this basis, Mr. Broeska's appointment as principal investigator was terminated. The notice cited concerns about

Mr. Broeska not being present at the research site and not having a medical degree. It also noted that CTP Study participants were being advised to discontinue medications in inappropriate circumstances, were not being followed-up and in some cases had their diagnoses manipulated.

75. Dr. Krause's involvement in Clinicard, Regenetek, Regenetek Research Inc. and the CCSVI Clinic terminated after January of 2015 when she returned from a trip to Trinidad and Tobago. Dr. Krause is quoted by the media as saying that she was "duped" by Mr. Broeska and described as being "shocked by news Mr. Broeska inflated his credentials, overstated the effects of the stem cell treatment and was asked recently by an Indian ethics committee to resign as the study's principal investigator because he put patient safety at risk". Dr. Krause has also stated that she terminated her relationship with Mr. Broeska and has not been in contact with him since January 2015.

#### Dr. Krause's Misconduct Involving Specific Patients

76. During the College's investigation, evidence was provided to the College relating to Dr. Krause's direct involvement with respect to 19 individual patients. In those cases, Dr. Krause was either actively involved with their participation in the CTP Study and/or provided them with medical advice in circumstances in which her personal and financial interests conflicted with their interests as patients or prospective patients.
77. For most of the listed patients, the College had to rely solely upon evidence produced by Dr. Krause to determine the nature and extent of her involvement with Regenetek and the patients that participated in the CTP Study. The evidence largely consisted of several hundred e-mail threads provided by Dr. Krause for the period 2009-2015. Several common themes arise (all of which were known to Dr. Krause) with respect to Regenetek's patient communications upon review of the e-mails provided:

- (a) Mr. Broeska represents himself as “Dr. B” or Dr. Doug. He is not a medical doctor and whether he has a valid PhD in Health Administration is unknown;
  - (b) at Mr. Broeska’s request, Dr. Krause often provided medical advice to CTP Study participants through Mr. Broeska in a manner which made it appear as though the advice came from Mr. Broeska, when in fact it came from Dr. Krause;
  - (c) medical advice is provided to people via social media websites; and
  - (d) patients that reported they were not benefitting from the CTP were advised their symptoms could be attributed to something other than their neurological illness, including other pre-existing conditions or consumption of foods and other substances which were interfering with the function of the stem cells.
78. In many of the e-mail communications authored by Mr. Broeska, concerning which Dr. Krause either directly participated or would have been aware of at the time they were transmitted, Mr. Broeska refers to himself with the title ‘Dr.’ when communicating with patients or prospective patients. Neither he nor Dr. Krause, at any time, clarified in any of those e-mails to patients that Mr. Broeska was not a medical Dr., even in situations where patients were clearly looking to Mr. Broeska for medical advice.
79. Frequently, where patients were provided medical advice, patient concerns were received by Mr. Broeska, who the patient was looking to for medical advice, who would then forward the e-mails to Dr. Krause to formulate the medical opinion. Dr. Krause would then provide the opinion to Mr. Broeska to send to the patient.
80. In all cases where Dr. Krause gave medical advice:

- (a) Dr. Krause did not maintain a medical record with respect to any of the advice she provided.
  - (b) Dr. Krause ought to have known that much of the medical advice she was giving, especially in relation to the manner in which the stem cells were reacting, was unsupported.
81. The Agreed Statement of Facts filed as an exhibit in these proceedings, contained detailed and extensive facts relating to the nature and extent of Dr. Krause's involvement with each of the 19 individual patients. It is not necessary for the purpose of these Reasons for the facts relating to all of those 19 patients to be summarized herein. However to provide a factual context for the analysis which follows, a factual summary of Dr. Krause's involvement with a sample of those patients is outlined below.

*PATIENT A*

82. Patient A was the common law partner of Dr. Krause's brother. She suffered from an unidentified neurological illness and underwent treatment with the CTP in Pune, India in September of 2012.
83. On March 13, 2012, Patient A wrote to Mr. Broeska asking about poor reviews published on the internet concerning the hospital at which the CTP was performed. Mr. Broeska forwarded the e-mail to Dr. Krause and also responded to it himself, stating that the facility provided above standard care and dismissing the poor reviews. Dr. Krause responded to Patient A's correspondence, stating:

"Entertaining new and innovative medical techniques is always a journey that needs careful thought. There's no question that Stem Cell therapy for ALS/MS and other neurodegenerative diseases is new to North America. Docs in India, Europe and Israel have been doing it for several years, with very good results.

[Doctor] is very known in his field. Noble hospital is completely professional in its approach to this area of medicine, and all that Mr. Broeska has said is accurate.

With regards to the YouTube clip with [Doctor]. Many North American physicians, including Canadians will market their techniques in the same or similar ways, as [Doctor]. For some, this may be seen as unprofessional, but it is not unethical or improper medical practice, even from a Canadian medical licensing point of view, and we are fairly strict.”

84. Between May and September 2012, Dr. Krause continued to assist Patient A plan her trip to Pune, India to undergo the CTP, assisted with the fundraising efforts for the \$15,000.00 (CAD) paid to Clinicard for Patient A's participation in the CTP Study by purchasing an auctioned painting for \$150.00. She also personally paid for Patient A's travel to Pune, India in the approximate amount of \$4,300.00.
85. On January 23, 2014, Dr. Krause was provided images from an MRI scan that Patient A underwent.
86. Between October and December 2014, Dr. Krause assisted Patient A with obtaining physiotherapy.
87. From as early as September 2012, Dr. Krause assisted in the production of promotional videos featuring Patient A. At least three of these videos were published on the internet. Dr. Krause was present for the filming of at least one promotional video and is shown with Patient A. The promotional videos were used extensively in the efforts to recruit patients to the CTP and encourage investors to invest in the business of Regenetek and/or Regenetek Research Inc.
88. Patient A died in October 2015.

*PATIENT C*

89. Dr. Krause was aware that Patient C suffered from MS and underwent treatment with the CTP in Pune, India in September 2012. Patient C paid approximately \$15,000.00 or more to participate in the CTP Study.
90. Dr. Krause facilitated and encouraged Patient C's participation in the CTP Study and Patient C receiving the CTP treatment in Pune, India, by:
  - (a) consulting with Mr. Broeska via e-mail on October 24, 2010 about an information letter to be sent to Patient C related to diagnostic criteria for the CTP;
  - (b) meeting with Patient C and Mr. Broeska on one occasion prior to Patient C obtaining the CTP in August of 2012 and participating in exaggerating the benefits associated with the CTP and post-CTP physiotherapy regime to Patient C. Patient C states she was advised at this meeting that she could pay additional funds to have more stem cells and improve her prospects of recovery.
91. Patient C has stated that, at the pre-procedure meeting and in the presence of Dr. Krause:
  - (a) Patient C was advised that the CTP would essentially cure her secondary progressive MS.
  - (b) Mr. Broeska showed Patient C a video of a patient that received treatment in South America for Parkinson's disease as part of his promotion of the CTP.
  - (c) Patient C was advised the procedure would cost her approximately \$15,000.00, which was a discounted price offered in consideration for her low-income status.

- (d) Patient C was also advised that if she could raise a further \$6,000.00 an additional number of stem cells could be injected to improve prospective outcome during the procedure.
  - (e) She was further advised the operation would be followed by an important course of physiotherapy that was essential to obtain optimal benefit.
92. Patient C underwent the CTP procedure at the CCSVI Clinic in the fall of 2012. Patient C states that:
- (a) no thorough examination of her condition was undertaken pre-procedure and that Mr. Broeska had only been provided the materials she presented to him that she had from other care providers.
  - (b) After the procedure was done:
    - (i) practitioners at the hospital in India examined her superficially and made a video of her walking in a hallway. No such video was made prior to the surgery;
    - (ii) she initially felt that she did have some benefit in terms of strength and posture, however in retrospect she feels this was nothing more than placebo.
  - (c) Patient C feels she was misled about the benefits of the treatment and that she did not actually benefit from the treatment.
93. Dr. Krause met with Patient C on two occasions in November 2012 and in November 2013 after Patient C received the CTP and provided Patient C with medical advice about the CTP and the CTP Study and whether Patient C should undergo a second CTP treatment at the CCSVI Clinic given Patient C's lack of a positive response to the CTP, and Patient C's diet and exercise.

*PATIENT D*

94. Dr. Krause was aware that Patient D suffered from MS and underwent treatment with the CTP in Pune, India in September 2013. Patient D paid approximately \$25,000.00 (USD) or more, to Clinicard to obtain CTP and participate in the CTP Study.
95. On or about August 18, 2013, Dr. Krause provided medical advice to Mr. Broeska to communicate to Patient D that related to Patient D participating in the CTP Study, including information about UTI prophylaxis, hair loss and advising that Patient D's haemoglobin and thyroid status should be checked considering reported hair loss. This was in response to an inquiry Patient D made to Mr. Broeska about hair loss, in which she also advised she was taking Gabapentin and Fampyra.
96. During two in person meetings involving Dr. Krause, Mr. Broeska and Patient D, on or about November 8, 2013 and in or about March 2014, Patient D has stated that Dr. Krause participated in discussions related to Patient D's progress and the effects of some of Patient D's medications on the stem cells that had been transplanted during the CTP procedure. Patient D states that Dr. Krause and Mr. Broeska provided Patient D reassurances about the efficacy of the CTP procedure at these encounters when Patient D advised them of her lack of improvement.
97. On November 23, 2013, Dr. Krause provided medical advice to Mr. Broeska to communicate to Patient D, stating that Patient D was having an "exaggerated" response to the normal healing and regeneration of the muscles involved and suggesting that Patient D should engage in stretching and a short course of Clonazepam. This was in response to an inquiry Patient D made to Mr. Broeska about muscle spasticity in her legs.
98. Dr. Krause participated in advising Patient D to take a lower dose of Gabapentin as it may have been affecting the stem cells and to stop taking Fampyra.

99. Dr. Krause visited Patient D in hospital on two occasions between August and September 5, 2014 at Patient D's request. Patient D states that Dr. Krause requested that Patient D keep the visits confidential. Patient D was in the hospital in relation to a UTI, exacerbation of her MS symptoms and leg stiffness. Dr. Krause collected discs and written results from two of Patient D's MRIs while visiting her in hospital. These were to be considered in the context of her participation in the CTP Study and/or the Physiotherapy Study. Patient D states that she was advised by Dr. Krause that her MRIs would be reviewed for other possible causes of stiffness.
100. On or about September 24, 2014, Dr. Krause, via Facebook, commented in response to a question posted by Patient D about whether Patient D should take tranexamic acid.
101. On or about November 3, 2014, Dr. Krause provided medical advice to Mr. Broeska to communicate to Patient D, attributing Patient D's stiffness to Patient D suffering from degenerative disc disease and spinal stenosis and recommending a dosage of Gabapentin that Patient D should take and that Patient D do stretching and strengthening exercises.
102. Dr. Krause did not maintain a medical record with respect to any of the advice she provided.

#### *PATIENT L*

103. Dr. Krause was aware that Patient L suffered from ALS and underwent treatment with CTP in Pune, India in June of 2014. Patient L paid \$45,000 (USD) to Clinicard to participate in the CTP Study, receive the CTP and a post-CTP course of physiotherapy. Patient L's husband states that Dr. Krause was aware of the amount paid prior to Patient L travelling to India. Dr. Krause does not recall being aware of the amount paid by Patient L.

104. Dr. Krause first became aware of Patient L in March of 2014, when Mr. Broeska wrote to her indicating he had been in contact with Patient L's husband and was advised that Patient L had bulbar onset ALS. Dr. Krause responded to Mr. Broeska on March 3, 2014 stating, "yes ... with regards to the patient with ALS she most definitely requires to be treated ASAP before her symptoms become any worse." On March 24, 2014, in the context of Patient L's application to enroll in the CTP Study, Dr. Krause advised Mr. Broeska that she would be "more than happy to meet with yourself, [Patient L's husband] and [Patient L] over coffee to furthering discussion and answering questions". That meeting occurred on March 27, 2014.
105. On April 8, 2014, Patient L's husband wrote to Dr. Krause stating that to complete Patient L's India visa application, he needed a "Letter from the register Doctor/Hospital in Canada advising specialized treatment to be carried out in India with medical history" and asking if Dr. Krause could assist with this requirement. Dr. Krause responded indicating, "I'm not at all concerned about you or [Patient L], I'm concerned about the College of Physicians and Surgeons of Manitoba getting wind of my association with a treatment that is unsanctioned in Canada. Especially as [Patient L's] is not my patient. Now, having said that, there should be no reason for that to happen, but in Winnipeg there appears to be very few degrees of separation. I will work on some wording that will hopefully suffice."
106. On April 10, 2014, Dr. Krause used her position as a physician to facilitate the participation of Patient L in the CTP Study when she created and executed a letter in support of Patient L's application for medical visa to allow Patient L to travel to Pune, India to receive the CTP after she had specifically stated to the College in June 2013 that she would not write any such letters.
107. Both Dr. Krause and Mr. Broeska met with Patient L and Patient L's husband on several occasions and jointly persuaded them that the CTP

procedure would benefit Patient L's ALS. While Patient L's husband was skeptical about Mr. Broeska, he felt upon meeting and taking with Dr. Krause that she was the "real deal" and he and his wife trusted her in the process. Patient L underwent the CTP procedure in India between June 5 and 25, 2014.

108. On July 27, 2014, Dr. Krause wrote to Patient L and Patient's L's husband, stating:

"[...]

Very glad to hear that [Patient L]'s neck muscle strength is

holding, but somewhat disappointed that there has not been a more positive response to date. However, it's still early days and improvement is still to be anticipated and hoped for.

[...]"

109. On July 28, 2014, Dr. Krause provided Patient L with medical advice about Retigabine.
110. On August 25, 2014 Dr. Krause provided Patient L with medical advice about Riluzole and Scopolamine, and specifically recommended that Patient L cease taking Riluzole, a medication which was prescribed to Patient L in an attempt to slow down the progression of her ALS and prolong survival.
111. Following the June 2014 CTP procedure, Patient L did not realize any significant benefit from the CTP procedure. Patient L's husband states that Mr. Broeska and Dr. Krause advised Patient L and him that Patient L was the first person who didn't respond to the treatment. Dr. Krause states that Mr. Broeska offered, in Dr. Krause's presence, a second procedure be performed at the Clinic being opened by Regenetek in Trinidad and Tobago, which Patient L declined.
112. Patient L passed away in April 2015.

*PATIENT Q*

113. In respect to Patient Q, on or about November 5, 2014, Dr. Krause:

- (a) provided medical advice to Mr. Broeska to communicate to Patient Q regarding Rituximab, Epstein-Barr virus (“EBV”), H6, MS, and the CTP treatment, including specifically indicating that Rituximab would not exclude Patient Q from the CTP Study as long as Patient Q went off that medication for a period of 100 days leading up to the CTP treatment; and
- (b) minimized evidence related to the involvement of the EBV and HH6 viruses in MS pathogenesis;

which advice Dr. Krause knew, or ought to have known, would likely influence Patient Q’s decision as to whether to participate in the CTP Study.

Dr. Krause’s Approach to the College’s Investigation*GENERAL*

114. On January 19, 2015, the Registrar of the College referred concerns relating to Dr. Krause’s conduct to the College’s Investigation Committee. The referral identified the following concerns:

- (i) Dr. Krause’s involvement with Mr. Broeska, Clinicard, Regenetek, the CCSVI Clinic and CTP Study. Among other things, the Registrar’s referral identified concerns about medical advice Dr. Krause had provided to the CTP Study participants in the context of her business relationship with the CCSVI Clinic, Clinicard and Regenetek;
- (ii) Dr. Krause having previously provided misleading information to the College in 2013 when she had responded to a complaint that was brought by Patient B, which had been closed, based in part on information provided by Dr. Krause.

Dr. Krause was provided with written notice of the Registrar's referral of these concerns to the Investigation Committee by letter dated January 20, 2015.

115. Dr. Krause was required to respond within a fixed period of time. She requested an extension in January 2015 on the basis that she was not well enough to respond. A report was received from her psychiatrist. Dr. Krause signed an undertaking not to practice and not to have any contact with any patient or prospective patient of CCSVI Clinic or Regenetek Research. She agreed to produce documentation and a list of patients with whom she'd had contact and to provide her written response at a later time.
116. Hundreds of e-mail threads from Dr. Krause, the complainants and various other witnesses relevant to this matter were ultimately provided to the College during its investigation. Witnesses also provided the College with significant information in writing and interviews.
117. Between February 23, 2015 and April 18, 2017, Dr. Krause provided written responses to the Registrar's referral and patient complaints and was interviewed on four occasions. In her responses, she denied significant involvement with Clinicard, Regenetek, CCSVI Clinic and the patients that underwent the CTP procedure, often characterizing herself as nothing more than an investor or observer. Dr. Krause impeded and failed to cooperate with the College's investigation throughout and intentionally provided information and made statements to the College that were false or misleading:
  - (a) Dr. Krause maintained throughout the College's investigations, in two written responses to the College, and in two interviews on June 18 and August 26, 2015 with the College's investigator, that she had no role or a minimal role in the business affairs of Clinicard, Regenetek, and the CCSVI Clinic, stating that she was just an observer in relation to the CTP procedure and the CTP Study and that she was merely an investor in Clinicard and Regenetek. In fact

Dr. Krause had ongoing and substantial involvement in the operations of the entities and of the CTP Study.

- (b) Dr. Krause maintained throughout the College's investigation in written responses to the College and during interviews with the College's investigator on June 18, 2015 and April 18, 2017, that she was unaware of Regenetek's involvement in the recruitment of patients and that she was at no time personally involved in the recruitment of patients or the CTP Study. In fact, Dr. Krause was aware of and participated in Regenetek's activities, including but not limited to participating in meetings with patients, vetting prospective patients, addressing concerns raised by patients, making representations about the potential benefits of the CTP procedure and CTP Study and developing promotional videos for Regenetek and the CTP Study.
- (c) Dr. Krause maintained throughout the College's investigation in various written responses to patient complaints and the Registrar's referral and during her interviews with the College's investigator on June 18, 2015 and April 18, 2017, that she had a minimal role and little knowledge of the development and operation of the CTP procedure and the CTP Study. In fact Dr. Krause had been involved in the creation of the CTP procedure and CTP Study with Mr. Broeska and Regenetek from an early stage and had been a researcher in the CTP Study.
- (d) Dr. Krause took inconsistent and misleading positions as to her belief in the legitimacy of the CTP Study during the College's investigations.
- (e) Between February 23, 2015 and September 15, 2016, in written communications with the College and in June and August, 2015 interviews with the College's investigator, Dr. Krause maintained that

she did not provide medical advice to anyone involved in the CTP Study and that she was unaware that Regenetek provided medical advice to prospective clients. In fact she either provided that medical advice, directly or indirectly through Mr. Broeska, and she was aware that medical advice was being provided by Regenetek and Mr. Broeska. On September 15, 2016 and thereafter, Dr. Krause expressly admitted that she did provide medical advice to several patients and prospective patients.

- (f) Dr. Krause maintained throughout the College's investigation, specifically in her February 23, 2015 response to the Registrar's referral and during her interview with the College investigator on June 18, 2015, that she was unaware of the fees paid by clients to Clinicard to participate in the CTP Study, when in fact she was aware of the amounts that at least some patients paid to be involved in the CTP Study and knew those patients could pay additional fees to receive additional stem cells for the CTP procedure.

#### *PATIENT L*

- 118. In Dr. Krause's response to the College's investigation of Patient L's husband's complaints, she initially denied the totality of the complaint regarding Patient L. She subsequently provided incomplete and misleading information relating to her interactions with Patient L and the nature of her involvement with Patient L and either failed to produce or was slow to produce relevant records regarding her involvement with Patient L, which contained proof of several of the allegations against her as outlined the Amended Notice of Inquiry.

#### *PATIENT A*

- 119. During the College's investigation and with respect to Patient A, Dr. Krause stated in her letter to the College, dated June 10, 2015, and in her interviews

with the College investigator on June 18, 2015, August 26, 2015 and September 23, 2016 that:

- (i) she did not speak to Patient A about the CTP procedure and had little contact with Patient A leading up to Patient A undergoing the CTP, when in fact she was fully aware of how Patient A discovered the CCSVI Clinic and was fully aware of all aspects of Patient A's engagement with the CCSVI Clinic, including details of Patient A's recruitment into and financing of her participation in the CTP Study; and
- (ii) she had no role in the preparation of the promotional video(s) which purported to represent Patient A's experience in the CTP Study and made no representations as to the state of Patient A's health, either prior to or subsequent to the care which Patient A received at CCSVI the Clinic. In fact Dr. Krause had significant involvement in the preparation of that video and made numerous representations about Patient A's health subsequent to Patient A having undergone the CTP.

#### Inconsistent Positions Taken Between Two Tribunals

- 120. The University of Manitoba investigated Dr. Krause from January 22, 2015, when it received a complaint about her conduct, through June of 2015, when it issued a final report. The investigation related to concerns about possible breaches of the University's policy on 'Responsible Conduct of Research' and its 'Code of Research Ethics'. That investigation concluded in June of 2015 and the report was rendered in relation to same on June 26, 2015.
- 121. Dr. Krause did not personally report that she was under investigation by the University of Manitoba to the College as would have been required pursuant to Article 17 of the College's Bylaw #1.

122. By letter dated June 28, 2016, the College demanded that Dr. Krause provide the University of Manitoba report. The report was provided by Dr. Krause on September 15, 2016.
123. Dr. Krause took positions and made statements to the College during its investigation into concerns about her conduct and participation in the CTP Study which were inconsistent or incompatible with statements that she made in concurrent proceedings undertaken by the University of Manitoba between May 1 and June 2015. Some of the information she provided to the University was false and misleading.

#### Failure to Produce Relevant Materials to the College

124. Dr. Krause was required, pursuant to her January 27, 2015, undertaking and requests from the College made pursuant to *The Medical Act*, dated January 20, 2015 and January 29, 2015, to disclose all relevant records in her possession and control to the College. This would have included records related to the operation of Regenetek, Clinicard, Regenetek Research Inc. and the CCSVI Clinic, including a list of all patients or prospective patients involved with the CTP Study with whom she had any written or oral contact and copies of any written contact, including copies of e-mails between Clinicard, CCSVI Clinic or Regenetek and the patients on which she was copied.
125. In written correspondence from her former lawyer dated February 6, 2015, the College was advised that a search of Dr. Krause's records had been conducted and all records found were being disclosed. Search terms used by that lawyer and Dr. Krause and described in that correspondence appeared to be comprehensive. However it was subsequently established that Dr. Krause did not produce a significant number of records that should have been disclosed and produced in the February 6, 2015 production.
126. Despite the search of records that took place prior to the February 6, 2015 production of records, several e-mail communications were subsequently

produced by Dr. Krause and her former lawyer, or others in the College's investigation that should have been provided in the initial production of records. Notably, various communications from Mr. Broeska to Dr. Krause that were produced on July 8, 2015 by Dr. Krause were inexplicably not part of the initial disclosure. An additional concern about the July 8, 2015 disclosure is that Dr. Krause was never able to find an e-mail that she claims was sent that by Mr. Broeska that would have attached an iteration of the CTP Study Protocol which Dr. Krause says did not bear her name. Dr. Krause produced further e-mails not previously provided on July 20, 2015 and August 18, 2017.

### Current Circumstances

127. Following Dr. Krause's receipt of the College's referral of its concerns relating to her involvement with the CCSVI Clinic, Regenetek and Clinicard to the Investigation Committee, Dr. Krause provided an undertaking to the College dated January 27, 2015 which, among other things stated: "I shall immediately cease to practice medicine and I shall not resume the practice of medicine, in Manitoba or elsewhere, until such time as I have the express written permission of the Investigation Chair to resume practice".
128. In early 2016, Dr. Krause sought and obtained the permission of the Investigation Chair to resume the practice of medicine for the limited purpose of providing surgical assists in the Winnipeg Regional Health Authority ("WRHA"). In March, 2016, Dr. Krause resumed to practice pursuant to an undertaking dated March 18, 2016 whereby she restricted her practice to providing surgical assists within the WRHA and, among other things, agreed to have "no contact, written or oral with any patient or prospective patient of the CCVSI Clinic or of Regenetek Research.
129. In or about the month of June, 2016, Dr. Krause was granted permission by the College to perform surgical assists outside the scope of the WRHA and signed a further undertaking dated June 1, 2016, which stated, among

several other things, that she would restrict her practice of medicine to providing surgical assists, that she would not resume the practice of medicine in any other capacity, in Manitoba or elsewhere, without first obtaining the express written permission of the Investigation Chair to resume practice on an expanded basis and that during the time the undertaking remained in effect, she would not have any contact, written or oral, with any patient or prospective patient of the CCVSI Clinic or Regenetek Research.

130. In December, 2017, the Investigation Chair of the College approved certain conditions pursuant to which Dr. Krause was permitted to expand her practice to general practice as an attending physician. Dr. Krause signed a further undertaking dated December 13, 2017, whereby she agreed to accept several conditions on her licence including, but not limited to:

- (i) practicing under the supervision of a designated physician, who was also required to sign an undertaking. Both undertakings outlined with particularity the nature and extent of the supervision required and outlined strict requirements to be fulfilled by Dr. Krause and the supervising physician, both within the first four months following Dr. Krause's commencement of her practice at a specified Winnipeg hospital, and less strict requirements, but nonetheless rigorous requirements, thereafter;
- (ii) restricting her practice of medicine to the role of CAU attending physician at a specified Winnipeg hospital;
- (iii) not engaging or participating in any clinical research;
- (iv) not providing medical advice pertaining to any non-traditional therapies;

- (v) refraining from any contact, written or oral, with any patient or prospective patient of the CCSVI Clinic, or Regenetek Research.

131. The undertaking signed by Dr. Krause dated December 13, 2017 expressly stipulated that it was to remain in effect until modified in writing or rescinded in writing by the College. Dr. Krause is continuing to practice under supervision as a CAU attending physician at a specified Winnipeg hospital pursuant to the terms of that undertaking.

### **CHARGE 8**

Charge 8 of the Amended Notice of Inquiry (to which Dr. Krause pleaded not guilty) alleges that by reason of the facts and matters referred to in charges 1 through 7 inclusive (to which Dr. Krause pleaded guilty) Dr. Krause demonstrated an incapacity or unfitness to practice medicine.

Charge 8 does not define a time period in which Dr. Krause demonstrated an incapacity or unfitness to practice medicine, because the College asserts that by virtue of the gravity of the charges, the varied nature of Dr. Krause's proven wrongdoings, and the extended period of time in which the misconduct and breaches of professional standards occurred, Dr. Krause demonstrated an incapacity or unfitness to practice medicine during the period of time covered by the charges (February, 2011 to April, 2017), which incapacity or unfitness will continue indefinitely.

It is relevant that Dr. Krause has pleaded guilty to charge 6, acknowledging that by reason of the facts and matters referred to in charge 1 through 5 inclusive, she has been unwilling or unable to fulfill the requirements of and/or be governed by the College. Her guilty plea to charge 6, was clearly appropriate, given the false and misleading statements which Dr. Krause has acknowledged making to the College (charge 3), her impeding or failing to cooperate with the College's investigation (charge 4) and her failure to comply with the College's demands to produce relevant records (charge 5).

Similarly, her plea of guilty to charge 7, of displaying a lack of knowledge of or a lack of skill and judgment in the practice of medicine, was appropriate. Such a charge usually arises in cases in which the misconduct and breaches of professional standards involve many and varied unacceptable behaviours, occurring over an extended period of time. Those factors are present in this case.

The College argues that the cumulative effect of the serious matters referred to in charges 1 through 7, and Dr. Krause's guilty plea to those charges demonstrates that Dr. Krause is incapable or unfit to practice medicine.

Dr. Krause submits otherwise. Her counsel argued on her behalf that apart from the matters referred to in the Amended Notice of Inquiry, which arose in a unique set of circumstances while she was under the malign influence of Mr. Broeska, Dr. Krause was a well respected family physician with an unblemished disciplinary record and was a highly valued teacher of medical learners.

As noted earlier in these Reasons, the Panel has concluded that charge 8 has been proven and that Dr. Krause is guilty of having demonstrated an incapacity or unfitness to practice medicine. The Panel's reasons for that conclusion can be summarized as follows:

- (i) The facts outlined in the Statement of Agreed Facts conclusively establish a pattern of extensive misconduct and breaches of professional standards covering a diverse set of circumstances, including inappropriate and/or unethical participation in a clinical research study, involvement with many patients in facilitating their participation in the CTP study by a variety of means including the provision of medical advice, in circumstances in which her personal and financial interests conflicted with those of the patients. The above noted misconduct was then compounded and exacerbated by Dr. Krause providing false and misleading information to the College in the course of the College's investigation into these

matters and multiple instances of Dr. Krause failing to properly comply with the College's demands for relevant records. All of these events occurred over an extended period of time, and most of her interactions with the College occurred after she had received legal advice with respect to her professional obligations in such circumstances. In short, the Panel has concluded that Dr. Krause's conduct was so gravely serious, her breaches of standards so concerning and diverse, and her disrespect of the College's processes so contemptuous, that Dr. Krause demonstrated an incapacity or unfitness to practice medicine, during the period in which those actions and behaviours occurred, namely from February 2011 to approximately April 2017.

- (ii) With respect to the argument that Dr. Krause was a respected family physician and valued teacher, with a clean disciplinary record prior to these proceedings, the Panel has noted that many of the serious allegations against Dr. Krause in the Amended Notice of Inquiry, particularly the extensive particulars with respect to charges 2 and 3 in the Amended Notice of Inquiry and the Statement of Agreed Facts, were committed in relation to patients, although those patients were not seeing Dr. Krause through her regular office practice of family medicine.
- (iii) Furthermore, charge 8 does not refer to an incapacity or unfitness to care for patients, but rather an incapacity or unfitness to practice medicine. The charge recognizes that a physician's professional responsibilities are not confined to the care of patients, but extend to other categories of the physician's professional responsibilities such as, in this case, participation in a clinical research study, the avoidance of

conflicts of interests, and full unconditional cooperation with the College in its investigative and regulatory activities. Dr. Krause's behaviour fell considerably short of the appropriate standard in all of the above noted respects.

### **SUBSECTION 59.6 OF THE MEDICAL ACT**

In the context of Dr. Krause's guilty plea to charges 1 through 7, and the Panel's finding that Dr. Krause is guilty of charge 8, the Panel must determine the Order or Orders to be granted under subsection 59.6 of the *Act*. The Panel received helpful submissions with respect to that issue from counsel for both parties.

In reaching its decision, the Panel was mindful of the objectives of such orders as they have been articulated in judicial authorities and in decisions of inquiry panels of various Colleges in other cases, both in Manitoba and in other jurisdictions.

Those objectives include:

- (i) The protection of the public. Orders under subsection 59.6 of the *Act* are not simply intended to protect the particular patients of the physician involved or those who are likely to come into contact with the physician, but are also intended to protect the public generally by maintaining high standards of competence and professional integrity among physicians;
- (ii) The punishment of the physician involved;
- (iii) Specific deterrence, in the sense of preventing the physician involved from committing similar acts of misconduct in the future;
- (iv) General deterrence, in the sense of informing and educating the profession generally as to the serious consequences

which will result from breaches of recognized standards of competent and ethical practice;

- (v) Protection of the public trust in the sense of preventing a loss of faith on the part of the public in the medical profession's ability to regulate itself;
- (vi) The rehabilitation of the physician involved in appropriate cases, recognizing that the public good is served by allowing properly trained and educated physicians to provide medical services to the public; and
- (vii) Proportionality between the conduct of the physician and the orders granted under subsection 59.6 of the *Act*.

The above-noted objectives are not a comprehensive list. In any particular case, other factors may also be relevant. Additional factors which are relevant in this case are:

- (a) The nature and gravity of the misconduct;
- (b) The impact of the misconduct on those affected by it;
- (c) The vulnerability of those affected by the misconduct;
- (d) The role of the physician in acknowledging or failing to acknowledge what had occurred; and
- (e) The disciplinary record of the physician.

## **ANALYSIS**

### **Introductory Comments**

As noted in the Introduction to these Reasons, various documents were marked as Exhibits in these proceedings, including a detailed Amended Notice of Inquiry

and a lengthy and extensive Statement of Agreed Facts. Those documents were extremely helpful in outlining the background facts and assisting the Panel in identifying and gaining an understanding of the important issues in these proceedings.

However, there was one feature of those documents on which the Panel would like to specifically comment. The wording of both the Amended Notice of Inquiry and the Statement of Agreed Facts sometimes displayed a tendency to conflate “research” and “treatment”.

One example of that tendency is a statement in count 4 of the Amended Notice of Inquiry referring to circumstances in which Dr. Krause was cooperating with the University of Manitoba in concurrent proceedings and making certain admissions about the nature and extent of her involvement with the operation of the CTP Study and her communications with “patients who sought and/or obtained treatment through participation in the CTP Study” (underlining added). In the Panel’s view, it is inaccurate to say that such participants in the CTP Study were receiving treatment as a result of their participation in the study.

The interventions which the participants in the Study received were not treatments. The value of those interventions as “treatments” had not been established. The value of any of those unproven interventions as “treatments”, were being purportedly assessed and evaluated as part of the CTP Study.

Similarly, although the repeated use of the term “patient” in the Amended Notice of Inquiry and in the Statement of Agreed Facts was appropriate in the sense of emphasizing that Dr. Krause, as a physician, was providing medical advice and information to those individuals, it was somewhat misleading in another respect. The use of the term “patient” could be taken to suggest that “the patients” would be receiving treatment or standard medical interventions once they began to participate in the research study. As previously noted, although the individuals referred to as “patients” who became participants in the research study undoubtedly hoped to receive a therapeutic benefit from

their participation in the study, the interventions they received as part of the study were not treatments.

Dr. Krause, as a physician, owed responsibilities to those individuals with respect to the medical advice and information which she provided, or failed to provide to them. However, as participants in a research study, those individuals should also have been told in clear and explicit terms by Dr. Krause, or someone else, that the interventions they would be receiving were not standard medical interventions and could not be considered to be treatments because the efficacy and benefits, if any, of the interventions had not yet been established. Indeed, it is the Panel's understanding that subsequently, a blind, controlled research study in Canada, assessing the effectiveness of Liberation Therapy in the treatment of MS patients established its failure to alter the clinical course of that disease, or to benefit patients in any way

It is the Panel's belief that it is important in these proceedings to be mindful of the distinction between therapy and treatment on the one hand and research and study on the other hand. It is important to do so in order to properly understand the seriousness of Dr. Krause's conduct and the diverse nature of the breaches she committed of various standards, including standards applying to her as a physician relating to conflict of interest and the provision of non-traditional therapy.

### The Positions of the Parties

In terms of the ultimate disposition of these matters, the parties assert contrary positions.

It is the position of the Investigation Committee that the revocation of Dr. Krause's registration on the Medical Register and of her license to practice medicine, is the only result which will properly fulfill the objectives of orders under subsection 59.6 of the *Act*. Moreover, revocation is the only disposition which will send the appropriate message to:

- (a) the participants in the CTP Study and the individuals who complained to the College about Dr. Krause's conduct;
- (b) Dr. Krause herself;
- (c) to the public in terms of the ability of the medical profession in Manitoba to govern itself; and
- (d) to the profession.

Counsel for the Investigation Committee also stresses that this is an appropriate case for an award of costs against Dr. Krause. The College intends to seek recovery from Dr. Krause of all of the costs it has incurred associated with these proceedings. Rather than asking for an order providing for a specific sum reflecting those costs, counsel for the Investigation Committee suggests that the order should award costs against Dr. Krause but afford the parties an opportunity to discuss and potentially agree upon an appropriate sum, but with the ability to attend before the Panel to make submissions on that issue if they are unable to agree on a specific sum.

In contrast, Dr. Krause submits that the appropriate disposition in this case would be to suspend her from the practice of medicine for a period of six months, subject to various conditions, including that she continue with psychiatric counselling either indefinitely, or until her treating psychiatrist indicates that counselling is no longer necessary, and that she return to practice under the same conditions which are currently in place, and have been in place since December 2017, as summarized earlier in these Reasons.

### Commentary

The Panel is satisfied beyond any doubt that Dr. Krause's misconduct as summarized in the "Background" section of these Reasons was extremely serious, not only in terms of the inherent gravity of the actions themselves, but also in terms of the

diverse nature of her breaches of various standards, and the extended time period over which the breaches occurred.

The finding that Dr. Krause is guilty of charge 1 in the Amended Notice of Inquiry relates to Dr. Krause's inappropriate and unethical participation in a research study to investigate unproven interventions for MS, ALS and other neurological illnesses. Charge 1 has multiple components, including:

- (i) The conflict of interest between Dr. Krause's personal and financial interests in Clinicard, Regenetek, the CCSVI Clinic and Regenetek Research and the interests of the individuals who were enrolled in the CTP Study and who hoped to receive a therapeutic benefit from participating in the Study.
- (ii) The failure by Dr. Krause to disclose the nature and extent of her involvement with Clinicard, Regenetek, the CCSVI Clinic and Regenetek Research, to participants and prospective participants in the CTP Study.
- (iii) The failure by Dr. Krause to objectively assess the design and implementation of the CTP Study with the rigour and experience a medical doctor would be expected to demonstrate and allowing her personal and financial interests to impair her ability to properly assess the legitimacy of CTP Study.
- (iv) Dr. Krause's participation or complicity in encouraging vulnerable individuals to undergo experimental, invasive and unproven interventions, creating unrealistic expectations in those patients with respect to potential benefits, and failing to adequately inform those individuals about the nature of the research being conducted in the CTP Study.

- (v) Dr. Krause's participation in the distribution of misleading information through the Regenetek website about the CTP Study, including articles and promotional videos.
- (vi) Dr. Krause's participation in the development and promotion of the Physiotherapy Study through Regenetek during which she failed to disclose her conflicts and potential conflicts of interest to various individuals and entities including the Ethics Review Board considering the Physiotherapy Study and the University of Winnipeg, where the Physiotherapy Study was to be conducted.

Charge 2 of the Amended Notice of Inquiry also involves multiple allegations against Dr. Krause, all of which have been proven. Charge 2 contained extensive factual particulars supported and buttressed by the evidence in the Statement of Agreed Facts, relating to 19 individuals, with whom Dr. Krause had various forms of interaction. Regardless of the form of interaction, Dr. Krause provided medical advice to those individuals and encouraged or facilitated their participation in the CTP Study.

All of those individuals were vulnerable. Many of them placed significant reliance on the information and advice being provided by Dr. Krause precisely because she was an experienced physician.

The submission by Ms Arnason, the lawyer for the Investigation Committee of the College, cautioning the Panel not to become "desensitized" to the seriousness of the evidence by virtue of the sheer volume of the evidence, resonated with the Panel. The evidence relating to all of the 19 individuals was all serious and very concerning.

Two matters warrant specific comment in that context.

- (i) In July and August, 2014, Dr. Krause provided medical advice to Patient L, who was suffering from ALS. Her advice related to Patient L's response to the CTP Interventions. Her advice included a recommendation that Patient L stop taking

Riluzole, a medication, which arguably has the effect of prolonging life in ALS patients. To provide such advice, in circumstances in which Dr. Krause's personal and business interests conflicted with her duties as a doctor and without proper regard for what was objectively in the best interests of Patient L, is a matter of profound concern to the Panel.

- (ii) All of the 19 individuals referred to in Charge 2 of the Amended Notice of Inquiry were susceptible to being unduly influenced by the advice being provided by Dr. Krause by virtue of her being an experienced physician. Dr. Krause exploited that susceptibility by encouraging their enrolment in a study which involved substantial fees and expenses for those individuals, lengthy travel (which was bound to be arduous given their compromised health), invasive and painful surgical interventions, accompanied by risk of physical harm. It is evident to the Panel that Dr. Krause's personal and financial self-interests prevailed over the well-being of those 19 individuals and seriously impaired her judgment and ability to assess the best interests of those individuals.

Charges 3, 4 and 5 of the Amended Notice of Inquiry relate to a failure on the part of Dr. Krause to cooperate with the College and to Dr. Krause providing false and misleading information to the College. The nature and extent of Dr. Krause's duplicity with the College is clear from the evidence outlined in pages 156-185 of the Statement of Agreed Facts.

Three aspects of those background facts are particularly alarming. They are:

- (i) Charge 3 relates to communications which Dr. Krause had with the College in 2013, at a time when the College had little information with respect to Dr. Krause's activities in relation to

Clinicard, Regenetek and the CCSVI Clinic. Dr. Krause deliberately provided false and misleading information to the College in response to a complaint from Patient B which caused the College to discontinue its investigation and to enable Dr. Krause to carry on with her activities relating to Clinicard, Regenetek, the CCSVI Clinic and the CTP Study.

- (ii) Charges 4 and 5 relate to investigations undertaken by the College between 2015 and 2017. The number of instances in which Dr. Krause failed to cooperate with the College or in which she provided incomplete or false information to the College is very disturbing. The pattern of deception is consistent with an intention on the part of Dr. Krause to prevent the College from learning the true facts while protecting her own position. Dr. Krause seldom responded to questions or requests from the College with the truth, or the whole truth, and was only fully forthcoming when confronted with irrefutable evidence establishing facts which were contrary to the version of events which she had previously put forward by Dr. Krause.
- (iii) Dr. Krause's lack of cooperation and deceit persisted for more than 4 years.

As noted elsewhere in these Reasons, the evidence relating to Charges 1 through 5 also support and establish guilt with respect to Charge 6 (relating to Dr. Krause's ungovernability by the College) Charge 7 (displaying a lack of skill and judgment in the practice of medicine) and Charge 8 (unfitness to practice medicine).

### Counterbalancing Considerations

In the face of the overwhelming evidence of serious misconduct by Dr. Krause, there are 3 potentially counterbalancing considerations, which the Panel has considered.

1. The first is Dr. Krause's lengthy and positive record as a practicing physician. She has been registered in the Manitoba Medical Register since July 1, 1978. She has practiced successfully, initially in emergency medicine, and since 1990, in family medicine. During that span of over 40 years, Dr. Krause has only been out of practice from January, 2015 to March, 2016 (although from March, 2016 to the present she has been practicing subject to restrictions and conditions).

During her career, apart from matters associated with these proceedings, Dr. Krause has practiced medicine within her preferred areas of practice safely and competently. She has a clean disciplinary record.

Prior to 2015, Dr. Krause had an impressive career as an award winning teacher of medical learners. She had significant teaching responsibilities at the Faculty of Medicine at the University of Manitoba, and held significant positions in the Family Medicine Program.

Counsel for the Investigation Committee made two important rebuttal submissions in relation to Dr. Krause's impressive career as a practicing physician and educator. They were:

- (i) Although Dr. Krause has a clean disciplinary record with the College, that is only because she failed to cooperate and made false and misleading statements to the College in relation to the 2013 complaint. Had she been truthful with the College during that investigation, her disciplinary record would likely not have remained unblemished; and

- (ii) Her positive record as a physician and medical educator “cuts both ways” because she has demonstrated the capacity to lead a “double life”. In other words, she can function competently and ethically in certain aspects of her life, but in others, particularly when her personal and financial interests intrude, she engages in misconduct and uses deceit to conceal her misconduct.

Notwithstanding those rebuttal remarks, the Panel is of the view that Dr. Krause’s lengthy and meritorious career as a family physician and as an educator must be given weight in its deliberations. Those aspects of her career demonstrate that in the past she has practiced medicine competently and ethically and that she may be an appropriate candidate for rehabilitation.

2. The second potentially counterbalancing consideration is that Dr. Krause is now under the care of a psychiatrist and has been since January, 2015. Her attending psychiatrist has provided reports which were introduced into evidence in these proceedings.

In 2015, Dr. Krause’s psychiatrist diagnosed her with a Major Depression and an Anxiety Disorder, for which he treated her with individual supportive psychotherapy and pharmacotherapy. Gradually Dr. Krause’s mental health improved. The medications have been discontinued, but the psychotherapy continues.

Dr. Krause’s psychiatrist initially considered other diagnoses, including a Bipolar illness.

Subsequently, Dr. Krause’s psychiatrist reaffirmed his initial diagnosis that Dr. Krause had been experiencing a Major Depression, and was suffering from Anxiety Disorder. He also subsequently diagnosed her as having Narcissistic Personality Traits. Dr. Krause’s psychiatrist stated that Dr. Krause’s Narcissistic Traits are characterized by poor self-esteem, a

fear of being shamed (leading her to minimize her unacceptable behaviours), fear of humiliation and avoidance of sensitive and painful topics.

In a letter dated April 29, 2016, Dr. Krause's psychiatrist reported that Dr. Krause's Depression and Anxiety were in remission and that in his opinion, Dr. Krause represented no danger to patient safety. In a letter dated July 27, 2016, Dr. Krause's psychiatrist outlined his opinion that Dr. Krause presented no danger to patient care. He also stated that in his opinion Dr. Krause could "safely return to the practice of Family Medicine".

In a letter dated October 17, 2018, Dr. Krause's psychiatrist opined among other things that: "Dr. Krause is making slow but steady progress" and "Dr. Krause's prognosis is good providing she continues with ongoing psychotherapy".

Dr. Krause relies on the reports of her psychiatrist to demonstrate that she is now acting responsibly and through psychotherapy is gaining insight into the factors which caused her misconduct. She is doing so to improve herself and to avoid a repetition of her transgressions. Dr. Krause also relies on the reports of her psychiatrist to establish that her prognosis is good, provided she continues with psychotherapy (which Dr. Krause has committed to do), and that she is able to practice family medicine competently and safely.

Counsel for the Investigation Committee minimized the significance of Dr. Krause's psychiatrist's reports and argued that they were of little assistance to the Panel in dealing with the all important question of whether Dr. Krause's registration and license to practice medicine ought to be revoked. Counsel for the Investigation Committee argued that:

- (i) Dr. Krause's psychiatrist has provided no opinion with respect to Dr. Krause's mental health status during the period prior to January, 2015, i.e. during the period when most of the

misconduct referred to in counts 1 and 2 of the Amended Notice of Inquiry occurred. As a consequence, the Panel has received no evidence that Dr. Krause's misconduct as outlined in those counts can be explained by a psychiatric illness or mental health condition or disorder.

- (ii) The College does not discount the opinions which Dr. Krause's psychiatrist has provided, but emphasizes that the opinions are qualified and limited. Dr. Krause's psychiatrist has confirmed that while Dr. Krause is progressing, her progress is slow.

The Panel has carefully considered Dr. Krause's psychiatrist's reports and opinions. The Panel is acutely conscious of the risks of placing undue reliance on these reports and opinions. The Panel recognizes the utility of Dr. Krause seeking psychiatric assessment and treatment and accepts that the treatment and psychotherapy she has received has been beneficial in improving her mental health status and helping her to gain insight into her personality and behaviours. However, the Panel is also aware of the limited nature of Dr. Krause's psychiatrist's opinions. The Panel also understands that psychotherapy has limits in terms of being able to fundamentally alter underlying personality traits.

3. The third potential counterbalancing consideration is the malign influence exerted by Mr. Broeska over Dr. Krause. Mr. Haight, counsel for Dr. Krause fairly characterized Mr. Broeska as an "effective conman". Mr. Haight suggested that Mr. Broeska's ability to exploit his romantic and financial entanglements with Dr. Krause, provides at least a partial explanation (but not an excuse) for Dr. Krause's misconduct.

Counsel for the Investigation Committee retorted that Dr. Krause is not the victim in these circumstances; the victims are the individuals who were persuaded to participate in the CTP Study.

The Panel has concluded that although Dr. Krause's relationship with Mr. Broeska is important in the factual context of these proceedings, Mr. Broeska's manipulations of Dr. Krause and others should not be an important factor in determining what orders the Panel ought to grant under ss.59.6 of *the Act*. The practice of medicine is stressful and challenging. Individuals in all walks of life face pressures and challenges, including challenges in their relationships with the people who are closest to them. Individuals who have been granted the privilege of practicing medicine cannot allow the dynamics of their inter-personal relationships to interfere with the fulfilment of their professional responsibilities and obligations.

### The Case Law

Both parties referred the Panel to various authorities, including judicial decisions, references from respected texts, decisions of inquiry panels of this College and of Colleges in other jurisdictions, and decisions from other professional regulators.

A review of other decisions is useful in providing information from other cases which may be similar to this case, by providing a comparative basis for determining a fair and reasonable result. Orders granted under subsection 59.6 of the *Act* should be proportionate to the conduct of the physician, i.e. they should not be excessively lenient, or excessively harsh relative to the conduct in question. A review of other cases provides examples of how other inquiry panels in Manitoba and elsewhere have sanctioned various types of misconduct. Therefore, a review of those other cases may assist in the analysis of proportionality.

However, the assistance provided by other cases has limits because different cases are never identical, either in terms of their background facts or other factors, such as the presence of aggravating and mitigating circumstances and the effects of the misconduct on patients and other third parties.

Counsel for the Investigation Committee referred to several authorities which involved:

- (a) Serious misconduct on the part of physicians or other professionals;
- (b) Significant adverse consequences for patients or other third parties; and
- (c) The revocation of the professional's license to practice his or her profession;

Some of the cases relied upon by the Investigation Committee involving physician misconduct involved the physician committing two or more types of misconduct, exacerbated by either false or misleading statements to investigator and/or a lack of cooperation with the investigation.

The background facts of this case can be distinguished from the facts of all of the cases referred to by the Investigation Committee in one or more important respects. However, the case of *The College of Physicians and Surgeons of Ontario v. Jamal, 2018 ONCPSD 21* is closely analogous to this case in several important respects.

Dr. Jamal's misconduct related to her involvement in three different research studies conducted by her in which she:

- (i) Intentionally manipulated data in each study with the intention of supporting the underlying study hypothesis;
- (ii) Altered patient records to match previously altered data sets;
- (iii) Deleted relevant evidence after she had knowledge her conduct was being investigated; and
- (iv) Used falsified results from one study to apply and obtain funding for the other studies.

In deciding that revocation was the appropriate penalty, the Ontario College placed significance, not only on Dr. Jamal's initial dishonesty in altering the research, but also on her repeated and deliberate attempts at a cover up. The Ontario College also

emphasized that her attempts to conceal her wrongdoing did not end until she was confronted with a comprehensive report by an Investigation Committee. Dr. Jamal's certificate of registration was revoked, although she had no prior disciplinary history and there were no concerns about her clinical competence.

In some respects, Dr. Krause's misconduct was more serious than the misconduct of Dr. Jamal. Dr. Krause's financial conflicts of interest were more stark. The participants in the CTP Study were arguably more vulnerable to financial and emotional exploitation than the participants in Dr. Jamal's studies.

There are distinguishing features between the two cases. Dr. Jamal had an extensive research background, whereas Dr. Krause did not. Dr. Jamal actively and deliberately falsified data. Furthermore, Dr. Jamal's transgressions were entirely her own, apparently uninfluenced by a manipulative third party like Mr. Broeska. Given those factors, it is arguable that Dr. Jamal had a greater appreciation of the nature and extent of her wrongdoing in a research setting, than did Dr. Krause.

Notwithstanding those differences, the Panel recognizes that the decision in the Jamal case is important. Therefore, it has been given significant weight in its deliberations.

The case on which counsel for Dr. Krause placed considerable emphasis was the 2018 decision of an inquiry panel of this College relating to *Dr. Gary Allan Joseph Harding*. In that case, Dr. Harding had entered a plea of no contest, and was ultimately found guilty of several charges, including professional misconduct, displaying a lack of knowledge or a lack of skill and judgment in the practice of medicine, and most significantly, of demonstrating unfitness to practice medicine.

Dr. Harding was an oncologist. His misconduct did not occur in the context of his oncology practice, but rather related to his actions as an Assistant Professor and an Associate Dean in the Faculty of Medicine at the University of Manitoba.

Dr. Harding committed various boundary violations in relation to two medical students in the Faculty of Medicine. He also provided medical advice to those students,

but failed to keep or maintain proper medical records relating to those students. In addition, he violated standards of practice relating to the prescribing of medications.

Pursuant to a joint recommendation made by counsel for the Investigation Committee and counsel for Dr. Harding, it was determined, among other things, that Dr. Harding should be suspended from the practice of medicine for a period of at least six months. It was also determined, that subject to the fulfillment of various preconditions (including psychiatric counselling, a comprehensive and satisfactory fitness to practice assessment and an interview with the Investigation Chair), Dr. Harding would be entitled to return to the practice of medicine. However, his practice would be subject to conditions designed to prevent a recurrence of his misconduct and to otherwise protect the public interest.

Counsel for Dr. Krause, emphasized the following features of the *Harding* case, as being instructive for the Panel:

- (i) Notwithstanding a finding that Dr. Harding had demonstrated unfitness to practice medicine, Dr. Harding's registration on the medical register and his license to practice medicine were not revoked. Rather, he was provided with a "path", although a very arduous path, for a potential return to the practice of medicine;
- (ii) Prior to the proceedings in question Dr. Harding, like Dr. Krause, had a clean disciplinary record. In addition, Dr. Harding's misconduct did not occur within his oncology practice; likewise Dr. Krause's misconduct did not occur within her family medicine practice; and
- (iii) A rehabilitative approach in physician misconduct cases may be appropriate in some cases, because the public good will often be served by a properly trained and experienced physician being able to provide medical services to the public. Dr. Harding was regarded as having rehabilitative potential. Dr. Krause's counsel submits that Dr. Krause has significant rehabilitative potential.

The Panel recognizes that there are important distinctions between the *Harding* case and this case. Nonetheless, the *Harding* case has been given significant weight in the Panel's deliberations.

Fulfilling the Objectives of Subsection 59.6 of the Act

The overriding purpose of Orders under subsection 59.6 of the *Act*, is to protect the public, both in terms of potential patients who may come into contact with the physician involved, and also in the broader sense of protecting the public generally by maintaining high standards of competence and integrity among physicians.

In this case, punishment and specific deterrence are also important objectives to be fulfilled. The gravity of Dr. Krause's misconduct requires punishment.

The Panel recognizes that Dr. Krause has experienced a humiliating loss of reputation, the termination of her career as a medical educator and that she has suffered seriously strained family relationships which have caused her much personal distress. In addition, she has lost the large amounts of money she advanced to Clinicard and Regenetek. She has also lost her home and most, if not all, of her savings. Although all of these things represent hardships, they are not punishments imposed by the College. Rather, they are the consequences of Dr. Krause's own actions and bad decisions.

Although the Panel is sensitive to the hardships which have been experienced by Dr. Krause, they cannot detract from the College's responsibility to govern her conduct and to punish her for her misconduct.

The Panel is mindful, not only of the seriousness of Dr. Krause's wrongdoing, but also of the vulnerability of the individuals whom she encouraged to participate in the CTP Study and the financial, emotional and physical harm which those individuals experienced by doing so.

Removal of Dr. Krause from the Medical Register and the revocation of her license to practice medicine are within the range of reasonable outcomes in this case.

Revocation would fulfill the objectives of punishment, specific deterrence and general deterrence.

Revocation would also be one way of protecting the public in both the narrow sense of preventing Dr. Krause from seeing patients and in the broader sense of maintaining high standards of competence and integrity within the medical profession.

The problem with revocation in this case is that it would prevent patients and prospective patients from accessing Dr. Krause's services as a family physician, an area of practice in which Dr. Krause has demonstrated skill and competence over many years.

The Panel has, therefore, considered whether there is an outcome, short of revocation, which will appropriately punish Dr. Krause for her misconduct and deter her and other physicians from similar behaviour, while still protecting the interests of the public and maintaining the public's confidence in the medical profession's ability to regulate itself.

In reflecting on that issue, the Panel considered four primary issues:

1. Does Dr. Krause have rehabilitative potential?
2. Is Dr. Krause likely to misconduct herself in the future?
3. Are there conditions which can be imposed upon Dr. Krause's license to practice medicine which will minimize the risk of future misconduct on her part?
4. Are any such conditions appropriate in this case given the nature and extent of Dr. Krause's past misconduct?

The Panel has concluded that Dr. Krause has substantial rehabilitative potential. She has skills and considerable experience as a family physician. She has practiced successfully and safely as a family physician for many years. Her treating psychiatrist has stated that she presents no danger to patient care and that she is able to

safely return to the practice of medicine. She has expressed remorse, which the Panel has concluded is genuine. She has committed to her own rehabilitation and has a desire to return to the practice of medicine. Dr. Krause's significant rehabilitative potential is also demonstrated by the fact that she has been practicing medicine on a limited basis since March 2016 and on a somewhat expanded basis, but under supervision and subject to strict conditions, since December 2017.

The Panel has also concluded that Dr. Krause is unlikely to misconduct herself in the future. She is no longer subject to the malevolence of Mr. Broeska. She has engaged in psychotherapy to gain insight into the factors, including her own personality traits, which contributed to her wrongful conduct. She has been forced to confront her own lack of training, knowledge, experience and competence as a researcher. She has endured the calamitous consequences of her flawed judgment and decision making which were undoubtedly adversely affected by her personal and financial conflicts of interest.

Given the foregoing, the Panel considers it very unlikely that Dr. Krause will misconduct herself in the future, either as she did in the past, or otherwise.

With respect to any potential conditions to be placed on her license to practice, Dr. Krause has acknowledged that the continuation of psychotherapy would necessarily be an absolute requirement.

The conditions pursuant to which Dr. Krause is currently practising, would also need to be in place (including, but not limited to, rigorous supervision by another designated physician, restricting her practice to the role of CAU attending physician at a specific facility, a prohibition against engaging or participating in any clinical research, a ban against providing medical advice pertaining to non-traditional therapies and refraining from contact with any patient or prospective patients of the CCSVI).

Although the above-noted conditions, and potentially others, would reduce the risk of Dr. Krause misconducting herself in the future, the Panel also considered

whether the imposition of any conditions are appropriate in this case, given the nature and extent of Dr. Krause's prior misconduct.

The Panel is aware of the proposition expressed in some of the authorities (e.g. *CPSM v. Ahluwalia*), that although conditions upon a physician's license to practice may be appropriate and effective in certain types of cases (such as those involving substance abuse by a physician, or the lack of skill in one particularly defined area of practice), they are not appropriate as a means of attempting to alter or regulate the behaviour which resulted in the misconduct in the first place. In other words, a physician who has committed serious acts of misconduct, but who wishes to be able to practice medicine, must demonstrate that he or she has meaningfully addressed the root causes of the prior problems, before any consideration of a return to practice subject to conditions should occur.

The Panel is well aware of the Investigation Committee's position that Dr. Krause's misconduct was varied and that much of it was likely caused by personality traits which are solidly entrenched. The Investigation Committee also refers to the false and misleading statements given by Dr. Krause to the College over an extended period of time as evidence that conditions would be an inappropriate and potentially ineffective expedient in this case. The Investigation Committee Asserts that conditions on her license cannot provide sufficient assurance that Dr. Krause will not revert to previous patterns of behaviour, particularly if Dr. Krause experiences additional pressures either in her personal or her professional life.

The Panel respectfully disagrees.

This case has unique features. The seriousness of Dr. Krause's misconduct and her disrespect of the College's investigative processes are indicative of character flaws and have resulted in findings by this Panel that Dr. Krause was ungovernable, had displayed a lack of knowledge of or a lack of skill and judgment in the practice of medicine and had demonstrated an incapacity or unfitness to practice medicine during the period the events referred to in the Amended Notice of Inquiry were occurring. However, Dr. Krause has taken steps to address the root causes of her misconduct, including the

narcissistic personality traits identified by Dr. Krause's psychiatrist. She is becoming aware of the manner in which those traits may have caused or contributed to her misconduct and is rehabilitating herself by way of the psychotherapy she has been receiving in the last few years.

The Panel has decided that a disposition which imposes a severe punishment, including a lengthy suspension of Dr. Krause's license to practice medicine, but which provides a path for her to return to the practice of medicine will properly fulfill the numerous objectives of subsection 59.6 of the *Act*. Strict and explicit conditions on her entitlement to practice medicine after the suspension, will also protect the public interest and preserve the public's faith in the medical profession's ability to govern itself.

In reaching this decision, the Panel has considered the cases referred to by the Investigation Committee, including *Jamal*, and the *Harding* decision, relied upon by Dr. Krause. In all of those cases, the physicians who had misconducted themselves had been the instigators or the primary agents of the wrongdoing which had occurred. In this case, Dr. Krause was not the driving force behind the CTP or the CTP Study. She was duped by Mr. Broeska because she failed to recognize how seriously her judgment had been compromised by her financial conflicts of interest and her personal relationship with Mr. Broeska. Those factors do not diminish the seriousness of her misconduct or relieve her of responsibility for her own actions and decisions, but they are matters which the Panel has taken into account when determining the orders to be granted under section 59.6 of the *Act*.

An order requiring Dr. Krause to pay all of the College's costs in relation to its investigations of these matters and the costs of these proceedings, will form part of the Panel's disposition. Such an order is required and appropriate in this case, because Dr. Krause's false and misleading statements to the College and her lack of cooperation with the investigations conducted by the College, made the investigations and these proceedings unduly protracted and expensive.

## **CONCLUSION AND DECISION**

Based on all of the foregoing, the Panel has decided that:

1. Pursuant to subsection 59.6(1)(b) of the *Act*, Dr. Krause shall be suspended from the practice of medicine commencing at 12:00 midnight on Friday, May 24, 2019, continuing for a period of 12 consecutive months.
2. During the period of the suspension, Dr. Krause shall continue with individual supportive, insight oriented psychotherapy with her current psychiatrist, or such other psychiatrist as may be agreed upon by Dr. Krause and the Investigation Committee.
3. Provided that Dr. Krause has continued with the psychotherapy referred to in the immediately preceding paragraph and that Dr. Krause's current psychiatrist (or any other psychiatrist who has provided such psychotherapy) is of the opinion that Dr. Krause is able to safely return to the practice of family medicine, Dr. Krause shall be entitled to return to the practice of family medicine commencing at 12:01 a.m. on May 25, 2020, subject to the conditions outlined below and as more particularly set forth in the Resolution and Order issued concurrently herewith.
4. Pursuant to subsection 59.6(1)(e) of the *Act*, if Dr. Krause returns to practice, conditions shall be imposed upon her entitlement to practice medicine which shall be identical or substantially similar to the conditions outlined in an Undertaking signed by Dr. Krause dated December 13, 2017, pursuant to which Dr. Krause has been practicing medicine from 2017 to the date hereof. Those conditions shall include:
  - (i) Dr. Krause practicing as a CAU attending physician in family medicine at a specified Winnipeg hospital, or such other hospital as may be approved by the Investigation Committee of the College (the "Investigation Committee") under supervision by a Practice Supervisor approved by the Investigation Committee. Both

Dr. Krause and the Practice Supervisor shall provide signed Undertakings to the College, the form and content of which will be identical or substantially similar to the Undertakings signed by Dr. Krause, and her Practice Supervisor in December 2017;

- (ii) Dr. Krause shall restrict her practice of medicine to her role as a CAU attending physician in family medicine at a specified Winnipeg hospital, or such other hospital as may be approved by the Investigation Committee;
- (iii) Dr. Krause shall not engage or participate in any clinical research;
- (iv) Dr. Krause shall not provide medical advice pertaining to any non-traditional therapies; and
- (v) Dr. Krause shall not have any contact, written or oral, with a patient or prospective patient of CCSVI Clinic or of Regenetek Research.

The conditions referred to in this paragraph, and as more particularly set forth in the Resolution and Order issued concurrently herewith, may be varied by the Investigation Committee to reflect any changes in the material circumstances which may occur from time to time.

5. Pursuant to subsection 59.6(2) of the *Act*, Dr. Krause shall pay any and all costs arising from or incidental to the conditions described in this Decision and the monitoring of those conditions by the Investigation Committee.
6. Pursuant to subsection 59.7 of the *Act*, Dr. Krause must pay to the College the full costs of the investigation and inquiry in such amount and on such terms and conditions as the Investigation Committee and Dr. Krause shall agree. Failing such agreement, either the Investigation Committee or Dr. Krause may seek a determination from the Panel as to the amount of the costs and the terms and conditions upon which those costs shall be paid.

7. There will be publication in the usual course as set out in the *Act*, including Dr. Krause's name, as determined by the Investigation Committee.

DATED this 16<sup>th</sup> day of April, 2019

IN THE MATTER OF:                    “*THE MEDICAL ACT, C.C.S.M.*”

AND IN THE MATTER OF:           DR. SUSAN GRAHAM KRAUSE, A MEMBER OF  
THE COLLEGE OF PHYSICIANS AND SURGEONS  
OF MANITOBA

AND IN THE MATTER OF:           AN AMENDED NOTICE OF INQUIRY DATED  
DECEMBER 13, 2017

**RESOLUTION AND ORDER OF THE INQUIRY PANEL**

**WHEREAS** Dr. Susan Graham Krause (“Dr. Krause”), a member of the College of Physicians and Surgeons of Manitoba (the “College”), was charged with professional misconduct and with contravening By-Law 1 of the College, the Code of Conduct of the College, the Code of Ethics of the College, Statements 124 and 108 of the College, and with displaying a lack of knowledge, skill and/or judgment in the practice of medicine, and with demonstrating unfitness to practice medicine, as more particularly outlined in an Amended Notice of Inquiry dated December 13, 2017;

**AND WHEREAS** Dr. Krause was summoned and appeared before an Inquiry Panel (the “Panel”) of the College with legal counsel, on November 2, 5 and 6, 2018;

**AND WHEREAS** the Amended Notice of Inquiry dated December 13, 2017, outlining the charges and particularizing the allegations against Dr. Krause was filed as an Exhibit in the hearing before the Panel;

**AND WHEREAS** Dr. Krause entered a plea of guilty to 7 of the 8 charges outlined in the Amended Notice of Inquiry and entered a plea of not guilty to the count alleging that she had demonstrated an incapacity or unfitness to practice medicine;

**AND WHEREAS** the Panel reviewed the Exhibits filed, including the Amended Notice of Inquiry, and a detailed Statement of Agreed Facts (consisting of 185 pages and 303 paragraphs) and three binders of additional supporting documents including, among other things, patient specific documents relating to 21 patients, and documents relating to the College's investigation into these matters from and after January 2015;

**AND WHEREAS** the Panel heard detailed submissions from counsel for the Investigation Committee of the College and from counsel for Dr. Krause, including submissions with respect to the charges to which Dr. Krause had pled guilty and the charge with respect to which Dr. Krause pled not guilty, and submissions with respect to the appropriate disposition and orders to be made under subsection 59.6(1) of *The Medical Act, CCSM* (the "Act");

**AND WHEREAS** the Panel is satisfied that charges 1 through 7 of the Amended Notice of Inquiry have been proven and that Dr. Krause is guilty of the charges referred to in paragraphs 1 through 7 of the Amended Notice of Inquiry;

**AND WHEREAS** the Panel is also satisfied that charge 8 in the Amended Notice of Inquiry has been proven and that Dr. Krause is guilty of having demonstrated an unfitness to practice medicine;

**AND WHEREAS** counsel for the Investigation Committee of the College made a motion pursuant to subsection 56(3) of the *Act* for an order protecting the identity of all patients and third parties who may be referred to in the proceedings, or who may be referred to in any of the Exhibits filed in the proceedings, or in any video, audio, or digital recordings to be viewed or referred to as part of the proceedings, except Doug Broeska and Surjo Banerjee;

**AND WHEREAS** Dr. Krause, through her counsel, consented to such and Order.

**NOW THEREFORE BE IT AND IT IS HEREBY RESOLVED AND ORDERED THAT:**

- i. Pursuant to subsection 56(3) of the *Act*, there shall be no disclosure of the names or other identifying information of any patients, or other third parties who may be referred to in the proceedings, or who may be referred to in any of the Exhibits filed in the proceedings, or in any video, audio or digital recordings to be viewed or referred to as part of the proceedings, except Doug Broeska and Surjo Banerjee.
- ii. Pursuant to subsection 59.6(1)(b) of the *Act*, Dr. Krause shall be suspended from the practice of medicine commencing at 12:00 midnight on Friday, May 24, 2019, continuing for a period of 12 consecutive months.
- iii. Pursuant to subsection 59.6(1)(d) of the *Act*, during the period of the suspension, Dr. Krause shall continue with individual supportive, insight oriented psychotherapy with her current psychiatrist, or such other psychiatrist as may be agree upon by Dr. Krause and the Investigation Committee.
- iv. Pursuant to subsection 59.6(1)(d), provided that Dr. Krause has continued with the psychotherapy referred to in the immediately preceding paragraph and that her current psychiatrist (or any other psychiatrist who has provided such psychotherapy), is of the opinion that Dr. Krause is able to safely return to the practice of family medicine, Dr. Krause shall be entitled to return to the practice of family medicine commencing at 12:01 a.m. on May 25, 2020, subject to the conditions outlined below.
- v. Pursuant to subsection 59.6(1)(e) of the *Act*, if Dr. Krause returns to practice, conditions shall be imposed upon her entitlement to practice medicine, which shall be identical or substantially similar to the conditions outlined in an Undertaking signed by Dr. Krause dated December 13, 2017, pursuant to which Dr. Krause has been practicing medicine from 2017 to the date hereof. Those conditions shall include:

Dr. Krause practising as a CAU attending physician in family medicine at a specified Winnipeg hospital, or such other hospital as may be approved by

the Investigation Committee of the College (the "Investigation Committee"), under supervision by a Practice Supervisor approved by the Investigation Committee. Both Dr. Krause and the Practice Supervisor shall provide signed Undertakings to the College, the form and content of which will be identical or substantially similar to the Undertakings signed by Dr. Krause and her Practice Supervisor in December 2017;

Dr. Krause shall cooperate with all aspects of the supervision of her practice by the Practice Supervisor in accordance with her Undertaking and in accordance with the Undertaking of her Practice Supervisor;

Dr. Krause shall follow any advice, instruction or guidance provided by her Practice Supervisor, in good faith and to the best of her ability. She shall only see patients at times when her Practice Supervisor is physically present at a specified Winnipeg hospital, or such other hospital as may be approved by the Investigation Committee, or when her Practice Supervisor is readily accessible by phone, with the exception that Dr. Krause may see patients at times when:

her Practice Supervisor is away for a period not greater than one day; or

her Practice Supervisor is away for a period greater than one day, provided that an alternate Practice Supervisor acceptable to the Investigation Committee, which approval must first be confirmed in writing, is present while Dr. Krause is seeing patients;

Dr. Krause shall not engage or participate in any clinical research;

Dr. Krause shall not provide medical advice pertaining to any non-traditional therapies; and

Dr. Krause shall not have any contact, written or oral, with a patient or prospective patient of CCSVI Clinic or of Regenetek Research.

The conditions referred to in this paragraph, may be varied by the Investigation Committee to reflect any changes in the material circumstances which may occur from time to time.

- vi. Pursuant to subsection 59.6(2) of the *Act*, Dr. Krause shall pay any and all costs arising from or incidental to the conditions described in this Decision and the monitoring of those conditions by the Investigation Committee.
- vii. Pursuant to subsection 59.7 of the *Act*, Dr. Krause must pay to the College the full costs of the investigation and hearing in such amount and on such terms and conditions as the Investigation Committee and Dr. Krause shall agree. Failing such agreement, either the Investigation Committee or Dr. Krause may seek a determination from the Panel as to the amount of the costs and the terms and conditions upon which those costs shall be paid.
- viii. There will be publication in the usual course as set out in the *Act*, including Dr. Krause's name, as determined by the Investigation Committee.

DATED this 16<sup>th</sup> day of April, 2019.